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| (71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One SciMed Place, Maple Grove, MN 55311 (US).  |  | (81) Designated States: AU, CA, JP, KR, MX, SG, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  |   |
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| (54) Title: STENT DELIVERY SYSTEM HAVING STENT SECUREMENT APPARATUS   |  |  |   |
|   |  |  |   |
| (57) Abstract   |  |  |   |
| <p>A system/assembly for delivery and deployment of an inflation expandable stent within a vessel, comprising a catheter having proximal and distal ends; a stent, inflation expandable from a delivery diameter to a deployment diameter, such that the delivery diameter is reduced from the deployment diameter for conforming the stent to the catheter, such that the stent, in its delivery diameter, is coaxially mounted on the catheter near the catheter distal end; an expandable inflation means coaxially mounted on the catheter axially within the stent, for expansion of the stent from the delivery diameter to the deployment diameter upon application of fluid deployment pressure to the inflation means; and a securement component coaxially mounted on the catheter, axially within the expandable inflation means, the securement component designed and adapted to provide a securement pressure to the stent in the delivery diameter to maintain the stent in position on the catheter during delivery to the deployment site.</p> |  |  |   |

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## STENT DELIVERY SYSTEM HAVING STENT SECUREMENT APPARATUS

The present application is a Continuation-in-part application based on  
5 U.S. Serial No. 08/807,791 filed February 28, 1997, U.S. Serial No. 08/702,150 filed  
August 23, 1996, U.S. Serial No. 08/697,453 filed August 23, 1996, and U.S. Serial No.  
08/701,979, filed August 23, 1997, all of which are incorporated by reference in their  
entirety.

10

### Field of the Invention

This invention relates to an assembly and method for delivering and  
deploying an inflation expandable stent, particularly within a lumen of a body vessel.  
More specifically, this invention relates to stent securement devices most notably  
positioned between the balloon and the inner shaft of the catheter.

15

### Background of the Invention

Stents and stent delivery assemblies are utilized in a number of medical  
procedures and situations, and as such their structure and function are well-known. A  
stent is a general cylindrical prosthesis introduced via a catheter into a lumen of a body  
20 vessel in a configuration having a generally reduced diameter and then expanded to the  
diameter of the vessel. In its expanded configuration, the stent supports and reinforces  
the vessel walls while maintaining the vessel in an open, unobstructed condition.

Both self-expanding and inflation expandable stents are well-known and  
widely available. Self-expanding stents must be maintained under positive external  
25 pressure in order to maintain their reduced diameter configuration during delivery of the  
stent to its deployment site. Inflation expandable stents (also known as balloon  
expandable stents) are crimped to their reduced diameter about the delivery catheter,  
positioned at the deployment site, and then expanded to the vessel by diameter by fluid  
inflation of the balloon positioned between the stent and the delivery catheter. The  
30 present invention is particularly concerned with enhanced stent securement and safer  
stent loading in the delivery and deployment of balloon expandable stents.

In angioplasty procedure, there may be restenosis of the artery, which either necessitates another angioplasty procedure, a surgical bi-pass procedure, or some method of repairing or strengthening the area. To prevent restenosis and strengthen the area, a physician can implant an intravascular prosthesis for maintaining vascular patency, i.e. a stent, inside the artery at the lesion. The stent is expanded to a larger diameter for placement in the vasculature, often by the balloon portion of the catheter. Stents delivered to a restricted coronary artery, expanded to a larger diameter as by a balloon catheter, and left in place in the artery at the site of a dilated lesion are shown in U.S. Patent No. 4,740,207 to Kreamer; U.S. Patent No. 5,007,926 to Derbyshire; U.S. Patent No. 4,733,665 to Palmaz; U.S. Patent No. 5,026,377 to Burton et al.; U.S. Patent No. 5,158,548 to Lau et al.; U.S. Patent No. 5,242,399 to Lau et al.; U.S. Patent No. 5,344,426 to Lau et al.; U.S. Patent No. 5,415,664 to Pinchuck; U.S. Patent No. 5,453,090 to Martinez et al.; U.S. Patent No. 4,950,227 to Savin; U.S. Patent No. 5,403,341 to Solar; U.S. Patent No. 5,108,416 to Ryan et al.; and European Patent Application No. 707837A1 to Scheiban, all of which are incorporated herein by reference. A stent particularly preferred for use with this invention is described in PCT Application No. 96/03092-A1, published 8 February 1996, the content of which is incorporated herein by reference.

In advancing a balloon expandable stent through a body vessel to the deployment site, there are a number of important considerations. The stent must be able to securely maintain its axial position on the delivery catheter. The stent, particularly its distal and proximal ends, are sometimes protected to prevent distortion of the stent, and minimize trauma to the vessel walls. Balloon expandable stent delivery and deployment assemblies are known which utilize restraining means that overlay the stent during delivery. U.S. Patent No. 4,950,227 to Savin et al., relates to a balloon expandable stent delivery system in which a sleeve overlaps the distal or proximal margin (or both) of the stent during delivery. During inflation of the stent at the deployment site, the stent margins are freed of the protective sleeve(s) and the sleeves then collapse toward the delivery catheter for removal. A number of balloon expandable stent delivery and deployment assemblies do not use overlaying restraining members, such as the Savin sleeves, to position the stent for delivery. European Patent Application No. EP 055

3960A1 to Lau et al., uses an elastic sheath interspaced between the balloon and the stent. The sheath is said to act as a barrier to protect the balloon from the stent, allow uniform stent expansion, decrease balloon deflation time, prevent undesirable balloon flattening upon deflation and provide a friction substrate for the stent. The Lau sheath 5 can be positioned on the inside or outside of the balloon. U.S. Patent No. 5,409,495 to Osborne, similarly uses an elastic sleeve or sheath surrounding and in contact with the balloon for controlling the balloon radial expansion. In addition, Osborne is said to use restraining bands or a pair of balloons to achieve controllable stent expansion characteristics. U.S. Patent No. 5,403,341 to Solar, relates to stent delivery and 10 deployment assembly which uses a retaining sheath positioned about opposite ends of the compressed state. The retaining sheaths of Solar are adapted to tear under pressure as the stent is radially expanded, thus releasing the stent for engagement with the sheaths. U.S. Patent No. 5,108,416 to Ryan et al. describes a stent introducer system which uses one or two flexible end caps and annular socket surrounding the balloon to position the stent 15 during introduction to the deployment site. The content of all of these patents is incorporated herein by reference.

In positioning a balloon expandable stent on the delivery catheter over the fluid expandable balloon, the stent must be smoothly and evenly crimped to closely conform to the overall profile of the catheter and the unexpanded balloon. It has been 20 noted that, due to physical properties of the material used in manufacturing the stent (typically a shaped memory metal, such as stainless steel or Nitinol<sup>TM</sup>) there is a certain amount of "recoil" of the stent despite the most careful and firm crimping. That is the stent evidences a tendency to slightly open up from the fully crimped position and once the crimping force has been released. For example, in the typical stent delivery and 25 deployment assembly, if the stent has been fully crimped to a diameter of approximately .0035", the stent has been observed to open up or recoil to approximately .0037". This phenomenon has been characterized as "recoil crimping". Due to recoil crimping to this slightly enlarged diameter, it can be understood that the stent tends to evidence a certain amount of looseness from its desired close adherence to the overall profile of the 30 underlying catheter and balloon. That is, the stent tends to have a perceptible relatively slack fit in its mounted and crimped position. During delivery, the stent can thus tend to

slip and dislocate from its desired position on the catheter or even become separate from the catheter, requiring further intervention by the physician.

According to the present invention, a securement device is secured over the inner catheter beneath the balloon to compensate for the undesired looseness or slack

5 that due to recoil crimping and to aid in securing the stent to the balloon, as well as protecting the balloon material from being sandwiched between the stent and any metal or protruding item which may be mounted on the inner shaft/guide wire lumen, for delivery of the stent. The securement devices secure the stent during tracking and

10 delivery and provide a good friction fit to the stent and insure good contact between the stent and underlying balloon and catheter, instead of merely crimping the stent onto the balloon and the underlying catheter and relying on the bulk of the flaccid balloon to hold the stent on.

The art referred to and/or described above is not intended to constitute an admission that any patent, publication or other information referred to herein is "prior art" with respect to this invention. In addition, this section should not be construed to mean that a search has been made or that no other pertinent information as defined in

15 37 C.F.R. §1.56(a) exists.

### Summary of the Invention

20 This invention concerns a catheter apparatus suitable for performing angioplasty and for delivery of stents to body cavities. In general, stents are prosthetic devices which can be positioned within a body cavity, for example, a blood vessel or in some other difficultly accessible place of the body of a living human or animal. The stent prosthesis is formed of a generally tubular body, the diameter of which can be

25 decreased or increased. Stents are particularly useful for permanently widening a vessel which is either in a narrowed state, or internally supporting a vessel damaged by an aneurysm. Such stents are typically introduced into the body cavity by use of a catheter. The catheter is usually of the balloon catheter type in which the balloon is utilized to expand the stent, which is positioned over the balloon for delivery, to place it in a

30 selected location in the body cavity. The present invention is particularly directed to improved arrangements for releasably attaching and securing the stent to the catheter to

facilitate delivery thereof, specifically having a securement device within the balloon.

The below identified embodiments all disclose improved means for securing the stent to the catheter during the delivery procedure.

In certain embodiments the stent is held in place on the catheter by means 5 of an enlarged mounting body carried within the balloon by the catheter shaft to which the stent and balloon are fitted. The stent is fitted over the balloon, as by crimping. According to the invention in some embodiments, the enlarged body is axially movable on the inner shaft of the catheter so that it can be retracted from the stent mounting area to provide a small profile for performing angioplasty. The catheter can then be 10 withdrawn; the enlarged body can be moved into the stent mounting area; the stent can be mounted and the catheter can be re-inserted to implant the stent. In other embodiments, the enlarged body can be arranged to be reducible and enlargeable in size rather than being movable. Alternatively, the movable mounting body may be carried outside the balloon. A catheter of this type makes possible a method in which, before 15 stent loading with the associated mounting body arranged to provide reduced diameter in the balloon region, the catheter may be used to dilate a lesion or the like. The catheter may be withdrawn and the mounting body may then be selectively manipulated to provide an enlarged diameter in the stent mounting region and a stent may be loaded onto the catheter. The catheter may be re-inserted to implant the stent. The catheter may be 20 withdrawn or left *in situ* and the mounting body may be manipulated to provide reduced diameter again and the catheter may be used for any post-dilation desired. Also, the catheter may be used multiple times in the procedure for dilation and stent implantation.

Another embodiment of the present invention is also an assembly for 25 delivery and deployment of an inflation expandable stent within a vessel. The assembly comprises a catheter, an expandable tube component mounted on the catheter, an expandable balloon mounted on the catheter and encompassing the tube component, and a stent mounted on the balloon. The catheter has proximal and distal ends. The stent is inflation expandable from a delivery diameter to a deployment diameter. The delivery diameter is reduced from the deployment diameter for conforming the stent to the 30 catheter. The stent, in its delivery diameter, is coaxially mounted on the catheter near the catheter distal end. The expandable balloon is coaxially mounted on the catheter axially

within the stent. The balloon is designed and adapted for expansion of the stent from the delivery diameter to the deployment diameter upon application of fluid deployment pressure to the balloon. The expandable tube component is coaxially mounted on the catheter, axially within the expandable balloon. The tube components is designed and 5 adapted for fluid expansion to provide a securement pressure to the stent in the delivery diameter to maintain the stent in position on the catheter during delivery to the deployment site. The expandable tube component is sized and constructed to be fluid expandable to no more than the delivery diameter. The tube component is essentially equal in length to the stent and the stent is positioned on the assembly essentially 10 coextensive with the tube component.

In another embodiment, this invention is a method for delivering and deploying a stent using an assembly as just described. A catheter is provided having proximal and distal ends. An expandable balloon is coaxially mounted on the catheter. An expandable tube component is coaxially mounted on the catheter, axially within the 15 expandable balloon. The balloon and the tube component are each in an unexpanded condition. A stent is provided which is expandable from a delivery diameter to a deployment diameter. The stent, in a diameter greater than the delivery diameter, is mounted on the balloon. The stent is collapsed to the delivery diameter to conform to an overall profile of the catheter, the tube component and the balloon. The tube component 20 is inflated to provide to the stent a securement pressure, to retain the stent on the assembly in the delivery diameter. The assembly is delivered to a deployment site. The balloon is inflated to expand the stent to its deployment diameter.

An alternative embodiment of present invention is also an assembly for delivery and deployment of an inflation expandable stent within a vessel. The assembly 25 comprises a catheter, an expandable balloon mounted on the catheter, a corrugated tubing mounted on the catheter beneath or within the balloon, and a stent mounted on the balloon. The catheter has proximal and distal ends. The stent is inflation expandable from a delivery diameter to a deployment diameter. The delivery diameter is reduced from the deployment diameter for conforming the stent to the catheter. The stent, in its 30 delivery diameter, is coaxially mounted on the catheter near the catheter distal end. The expandable balloon is coaxially mounted on the catheter axially within the stent. The

balloon is designed and adapted for expansion of the stent from the delivery diameter to the deployment diameter upon application of fluid deployment pressure to the balloon. The corrugated tubing is mounted and adhered coaxially onto the catheter and is situated between the balloon and the catheter itself. When the stent is crimped and loaded onto the balloon, the balloon is situated therefore between the stent and the corrugated tubing. The tubing is preferably essentially equal to the length of the stent and the stent is positioned on the assembly essentially co-extensive with the tube component. The tubing on the catheter effectively holds the stent in place, takes up the slack due to recoil and protects the balloon material from being damaged during crimping.

Still another embodiment of the present invention comprises an assembly for delivery and deployment of an inflation expandable stent. The assembly comprises a catheter having proximal and distal ends. An annular collar or the like is coaxially located on the catheter distal end. A fluid expandable balloon is coaxially mounted over the collar at the catheter distal end. The balloon is expandable from a contracted to an expanded state. A stent is coaxially mounted on the balloon. The stent is inflation expandable from a reduced to an enlarged condition, the reduced condition conforming the stent to the balloon, collar and catheter in the preferred embodiment. The stent has at least an end portion overlying the balloon. At least one cup is coaxially mounted on the catheter distal end. The cup has a first end portion which may overlie the stent end portion. The cup and collar are cooperatively constructed and arranged to retain the stent end portion on the catheter in the stent reduced condition when the balloon is in the contracted state. The balloon and catheter are cooperatively constructed and arranged to cause expansion of the balloon from the contracted to the expanded state to cause enlargement of the stent, including the stent end portion, from the reduced to the enlarged condition, and thereby release the stent end portion from the cup end portion. The cup may be axially spaced from the collar but preferably they are relatively close together. The second end portion of the cup may be fixed to the catheter. The cup may overlie at least a portion of the collar. The collar can be shaped as a single member with the catheter, that is integral with it or the collar may be a separate body mounted axially and positioned on the catheter. The collar may be a mounting ring or cylinder axially

positioned between stent end portions under the stent and balloon. The collar may be a sheath under the stent and balloon.

A further embodiment is also directed to improved arrangements for releasably attaching the stent to the catheter to facilitate delivery thereof. The stent is held in place on the catheter by means of an enlarged body carried by the catheter shaft within the balloon to which the stent and balloon are fitted, as by crimping in combination with one or more sleeves releasably overlying an end portion or portions of a stent and balloon.

10

#### Brief Description of the Figures

Figure 1 is an isometric view, a portion of which is enlarged and in longitudinal section, of a balloon catheter having a mounting body in a retracted position;

Figure 2 is an even more enlarged view in longitudinal cross-section of the distal end portion of the catheter of Figure 1;

15

Figure 3 is similar to Figure 2 but showing the mounting body advanced to receive a stent mounted on the balloon;

Figure 4 is an enlarged cross-sectional view of the distal end portion of the catheter of Figure 1 similar to that of enlarged view Figure 3 but showing the balloon in an expanded condition along with the expanded stent;

20

Figure 5 is a schematic showing of a preferred mounting body carried by the catheter shaft within the balloon, the body being spirally cut to improve flexibility;

Figure 6 is a schematic showing in cross-section of another embodiment of the invention with a mounting body positioned to receive a stent but with a stent not yet mounted;

25

Figure 7 is a schematic showing of another embodiment of the invention;

Figure 8 is a schematic showing of a means for conveniently crimping the stent on the embodiment shown in Figure 5;

Figure 9 is a schematic showing of yet another embodiment of the invention;

30

Figure 10 is a showing of another embodiment of a mounting body according to the invention;

Figure 11 is a schematic of an enlargeable mounting body which is not axially movable;

Figure 12 is a schematic of an alternate enlargeable mounting arrangement which is not axially movable;

5 Figures 13 and 14 are schematic showings of yet another embodiment in which the axially movable mounting body is carried outside the balloon;

Figures 15 and 16 are schematic showings of still yet another embodiment of the invention, and

Figures 17 and 18 are modified versions of the embodiment shown in  
10 Figure 11.

Figures 19-21 are modified versions of the securement means of the present invention.

15 Figure 22 is a side profile section showing a balloon expandable stent delivery and deployment assembly, with the stent crimped to delivery diameter onto the balloon, the underlying inflating component and the catheter and with the inflating tube component inflated to securement pressure.

Figure 23 is a side profile section, similar to Figure 22, with the balloon and the stent fully inflated to deployment diameter.

20 Figure 24 is a side profile section showing an alternative embodiment of a balloon expandable stent delivery and deployment assembly, having a tube component formed in several sections.

Figures 25, 26 and 27 are cross-sectional views taken along lines 4-4, 5-5 and 6-6 of Figure 24, respectively.

25 Figure 28 is a side profile section showing a balloon expandable stent delivery and deployment assembly, with the stent crimped to delivery diameter onto the balloon, the underlying tube component and the catheter.

Figure 29 is a side profile section, similar to Figure 28, with the balloon and the stent fully inflated to deployment diameter.

30 Figure 30 is a perspective view of the corrugated tubing of the present invention.

Figures 31-33 are side profile sections showing alternative embodiments of balloon expandable stent delivery and deployment assemblies, having the tubing component formed in a plurality of sections.

Figures 34-35 are side profile sections showing alternative embodiments 5 of the balloon expandable stent delivery and deployment assemblies, the tube component inflatable to add securement pressure.

Figure 36 is a side profile section showing a balloon expandable stent delivery and deployment assembly, with the stent crimped to delivery diameter onto the balloon, the underlying tube component and the catheter, and also having containment 10 sleeves covering the ends of the stent.

Figure 37 is a side profile section showing a balloon expandable stent delivery and deployment assembly, with the stent crimped to delivery diameter onto the balloon, the underlying tube component and the catheter, and also having a pull-back wire attached to the tube component.

15 Figure 38 is a longitudinal cross-section of a stent delivery and deployment assembly of this invention showing a catheter with a collar mounted at the catheter distal end, an uninflated balloon mounted on the catheter over the collar, an unexpanded stent mounted on the balloon abutting the collar and a cup overlying the stent proximal end portion.

20 Figure 39 is a longitudinal cross-section of another stent delivery and deployment assembly of this invention showing a catheter with a collar mounted as a mounting ring at the catheter distal end, an uninflated balloon mounted on the catheter over the mounting ring, an unexpanded stent mounted on the balloon overlying the mounting ring and a cup overlying the stent proximal end portion; note that the collar is 25 positioned closer to the cup than in Figure 38.

Figure 40 is a longitudinal profile in partial cross-section of an assembly similar to that of Figure 38, with a bulge formed under the uninflated balloon at the catheter distal end.

30 Figure 41 is a longitudinal profile in partial cross-section of the assembly shown in Figure 38 with the balloon inflated and the stent expanded, showing the cup end portion flared to release the stent.

Figure 42 is a longitudinal profile, similar to Figure 41, showing the cup end portion rolled proximally to release the stent.

Figure 43 is a longitudinal profile of yet another stent delivery and deployment assembly of this invention, with the balloon mounted on the catheter, which 5 has a collar formed as a tapered single enlarged piece on the catheter, an unexpanded stent mounted on the unexpanded balloon abutting the collar and a cylindrical sleeve overlying the stent proximal end portion.

Figure 44 is a longitudinal profile of the assembly of Figure 43 with the balloon inflated and the stent expanded, showing the sleeve moved proximally to release 10 the stent.

Figure 45 is a side profile of still another stent delivery and deployment assembly of this invention with the uninflated balloon mounted on the catheter which has two collars formed integrally with the catheter, an unexpanded stent mounted on the balloon abutting the collar and a cylindrical cup overlying the stent proximal end portion 15 and the underlying collar.

Figure 46 is a longitudinal profile of another stent delivery and deployment assembly of this invention with the uninflated balloon mounted on the catheter, an unexpanded stent mounted on the balloon, mounting a cylinder on the catheter and a pair of cups overlying the stent ends.

20 Figure 47 is an isometric view, a portion of which is enlarged and in longitudinal section, of a balloon catheter having a stent fixed to the catheter over the balloon;

Figure 48 is an even more enlarged view in longitudinal cross-section of the distal end portion of the catheter of Figure 47;

25 Figure 49 is a schematic showing of one form of retraction of the releasable sleeve upon expansion of the balloon;

Figure 50 is a schematic showing of another form of retraction of the releasable sleeve upon expansion of the balloon;

30 Figure 51 is yet another form of retraction of the releasable sleeve upon expansion of the balloon;

Figure 52 is a schematic showing of yet another form of retraction of the releasable sleeve upon expansion of the balloon;

Figure 53 is a schematic showing of a modified shape for the releasable sleeve;

5 Figure 54 is a schematic showing in cross-section of another embodiment of the invention with a stent not yet mounted;

Figure 55 is a schematic showing of another embodiment of the invention; and

10 Figure 56 is a schematic showing of yet another embodiment of the invention.

#### Description of the Preferred Embodiments

The present invention relates to stent securement devices, most notably positioned between the balloon and the inner shaft of the catheter. Individual elements of 15 the below disclosed embodiments are generally interchangeable if desired. Referring to Figures 1-4 an angioplasty and stent delivery catheter system generally indicated at 10 includes a balloon catheter 12 having a balloon 14 on a distal end portion generally indicated at 16. Figure 1 shows a proximal portion of the catheter at 12a and a distal portion 12b in enlarged view. Figures 2 and 3 show the distal end portion 16 in an even 20 more enlarged view. The illustrative catheter 12 is of the type known as a rapid exchange or single operator catheter. However, other types of catheters may be used, such as over the wire and fixed wire types. The balloon 14 is fixed to the catheter 12 by standard means. The balloon is shown in its contracted state in. A stent 18 is fixed about the balloon by crimping thereto. The stent has a larger expanded diameter which is 25 obtained when the balloon is expanded in the known manner. In Figures 1 and 2 catheter is shown prepared for performing angioplasty and in Figure 3 it is prepared for stent implantation.

In Figures 1 and 2, an axially movable mounting body 30 is shown in a position proximal to the end portion 16 of the catheter where a stent may be mounted. 30 The catheter includes at its proximal end a manifold, generally designated 13, as is known in the art. The manifold includes an inflation port 15 as is known in the art. A

wire 31 is attached to body 30 to enable remote (from the proximal catheter end) advancement and retraction of it axially on inner lumen 26 over which it slides. In the retracted position shown in Figures 1 and 2, the catheter has a low profile for performing angioplasty.

5        This position is a retracted position and is selected by operation of a pull wire 31. The retracted position of the mounting body may vary. To maximize the low profile of the distal end 16 of the catheter, the retracted position may be within the outer member 24.

10      After such a procedure, the balloon is deflated, the catheter is withdrawn and the mounting body is advanced by means of wire 31 to the stent mounting position shown in Figure 3. A stent 18 may then be fixed about the deflated balloon by crimping it thereto. The stent has a larger expanded diameter which is obtained when the balloon is again expanded in the known manner. That is, the stent is released from the catheter upon expansion of the balloon as shown in Figure 4 to be placed in a vessel at the desired 15 location. When the balloon is then again deflated, removal of the balloon and catheter may be accomplished, leaving the stent in place. Exemplary dimensions for the inner 26 is a diameter of  $\frac{1}{2}$ mm and for body 30 a diameter of  $\frac{3}{4}$ mm.

20      As is known in the art the balloon is either bonded at its ends by adhesive 22, respectively to the outer member 24 of the catheter and to the inner member 26 of the catheter in the manner as shown, or is made one-piece with the outer member as is known in the art. The catheter balloon may be inflated by fluid (gas or liquid) from an inflation port extending from a lumen 28 (seen in Figure 2 and 3) contained in the catheter shaft and opening into the balloon as shown, or by other known arrangements, depending on the design of the catheter. The details and mechanics of balloon inflation 25 and specific overall catheter construction will vary according to the particular design involved in any given instance, and are known in the art *per se*. Such details are only shown schematically herein. All variations are acceptable for use with this invention.

30      Any balloon expandable stent may be used with this invention. Many are known in the art including plastic and metal stents. Some are more well known such as the stainless steel stent shown in U.S. Patent 4,735,665; the wire stent shown in U.S. Patent 4,950,227; another metal stent shown in European Patent Application EP0 707

837 A1 and that shown in U.S. Patent 5,445,646, or U.S. Patent 5,242,451. All of these patents are incorporated herein by reference. Also, shape memory metal stents may be used. As already indicated the stent of PCT Application 960 3092 A1 is particularly preferred.

5        The stent is typically for example about 16mm long, while the balloon may be 20mm long for example. These dimensions, however, are merely representative for illustrative purposes only and are not meant to be limiting. The stent is positioned over the balloon portion of the dilatation catheter and gently crimped onto the balloon either by hand or with a tool such as a pliers or the like to be mounted for delivery as  
10      shown in Figure 3. The crimping may be readily accomplished by the physician during the procedure.

15      In accordance with this invention, mounting body 30, best seen in Figures 2 and 3, is included inside balloon 14 to provide a cushion and/or substrate of enlarged diameter relative to the stent to support and hold the stent and secure it during crimping and the delivery procedure. The mounting body may be axially movable proximally or distally from the position shown in Figure 3, proximally being preferred.

20      In the embodiment shown in Figures 1-3, mounting body 30 is cylindrical in form and takes the shape of a sleeve axially and slidably carried on inner lumen 26, providing an enlarged area or portion for receiving the balloon and stent when the latter is crimped to the balloon. Marker band 34 may also be included on inner 26 as shown. Any radiopaque material such as gold is useful for this purpose. A stop member 36 of generally conical shape or any other shape may also be included on the marker band 34 as shown to provide additional resistance to stent movement during delivery and to protect the leading edge of the stent during delivery. Polyethylene or the like is suitable  
25      for the stop member. Other marker arrangements and stop arrangements may be used as well.

30      Although, the material of the mounting body may be hard, it is preferably of any deformable thermoplastic material, preferably an elastomer material and more preferably of a relatively resilient elastomer material, e.g., lower durometer silicone. A preferred deformable thermoplastic material is high density polyethylene (HDPE). A preferred lower durometer silicone is in the form of tubing. The deformation of the

resilient material of the mounting body when the stent/balloon is crimped to it causes a radial outward force on the stent/balloon increasing the friction therebetween despite any recoil of the stent.

During stent delivery, the balloon catheter is advanced through and 5 positioned in a patient's vasculature so that the stent is adjacent to the portion of the vessel where treatment is to take place. The balloon is inflated to expand the stent to an enlarged diameter. When the stent has reached the desired diameter, the balloon is deflated so that the catheter may be removed leaving the stent in place.

Another embodiment of the invention is shown in Figure 5. In this 10 embodiment mounting body 30 is a spiral cut elastomer or other suitable material, such as a rigid or flexible plastic, to provide separation for flexibility in that portion of the catheter, allowing more easy movement or tracking around bends. The spiral cut may be only partly through the mounting body or may be all the way through as shown in Figure 5. Also, while stop member 36 is shown at the distal end portion of the catheter in this 15 embodiment, no stop member may be used.

Another similar version is shown in Figure 6 which includes a cylindrical mounting body 30 made up of a plurality of separate adjacent rings 30a held together by wire 31 which extends therethrough as shown with stops 29 to secure the rings together. Rings 30a may be individual bodies carried on the sheath or bodies cut from a cylinder to 20 partially separate them or fully separate them. Suitable arrangements may be made to wire 31 at each end of the body 30 to hold the rings together, as shown.

The embodiment shown in Figure 7 includes another feature based on the 25 geometry of the mounting body for further securing the stent upon crimping. This feature is referred to herein as "interlocking". That is, the stent may be interlocked to the mount so that the stent cannot slide proximally or distally on the balloon unless it is deformed, such as by expansion. This can be seen by perusing the structure shown in Figure 7 which includes the inner 26 having a two-piece mounting body made up of spaced mounting bodies 30a and 30b. These bodies are connected to each other by connection means 33 which may be a separate or integral cylindrical body of lesser 30 diameter or may be one or two or more relatively rigid wire members as shown. The spacing between bodies 30a and 30b allows portions of the stent 18 and balloon 14 to be

depressed or inserted between the bodies upon crimping of the stent thus forming an interlock against sliding of the stent axially or longitudinally before the stent is released.

The interlock formation or crimping is readily accomplished by any suitable means such as a two-piece die 40 shown in Figure 8 or the like.

5       Figure 9 demonstrates that more than a two-piece mounting body arrangement may be used if desired. In this embodiment, the mounting body is comprised of three spaced interconnected bodies 30a, 30b and 30c on the inner 26. Preferably in the embodiments of Figures 7 and 9, the mounting bodies will be ring-like in shape or cylindrical in shape although other configurations will be readily apparent to 10 those familiar with this art.

15       Referring now to Figure 10, another embodiment of a movable mounting body 30 is shown in the form of a rigid coil of plastic, metal or the like having a control wire 31, preferably integral therewith. When in the metal form, the coil may be coated with a polymer such as polyethylene or PTFE or enclosed in a polymeric sheath of similar material. The coil may be slidably received on the inner 26 similar in arrangement to that shown in the preceding Figures.

20       As already indicated, an alternate arrangement may be used in which the mounting body, instead of being movable, is designed to be enlargeable and reducible or collapsible, while remaining in a fixed position in the stent mounting area of the catheter. Figures 11 and 12 are directed to such an arrangement.

25       In Figure 11, an inner balloon 50 of smaller diameter than outer balloon 14 is mounted on the inner 26. Balloon 50 may have a separate inflation conduit 52 inside inner 26, preferably including a valving arrangement 54. Valve 54 may be a one-way valve allowing only inflation of balloon 50 if desired. However, inner 26 may serve as the inflation conduit as well. In addition to fully inflating the balloon, inner balloon 50 may also be partially inflated.

Figure 19 shows a modification to Fig. 11 in which two inner balloons 50a and 50b are included. Fig. 20 shows a modification in which two inflation valves 54a and 54b are included.

Figure 21 shows a full arrangement of inner balloon 50 in which a syringe 120 is inserted into the distal end of the liner 26 of the catheter. The syringe has at its ends blocks 122 and 124 to enable local pressurization of inner 26 to inflate balloon 50.

Figures 17 and 18 show an inner balloon 50 similar to the arrangement of 5 Figure 11 but the balloon 50 in Figure 17 has a narrow center portion and wide ends to provide a mounting shape similar to that of Figure 7. In Figure 17, balloon 50 is inflated and balloon 14 is partially inflated. In Figure 18, balloon 50 is inflated and balloon 14 is uninflated ready for stent loading. Balloon material is preferably a polyethylene or urethane elastomer such as Tecoflex or Tecothane from Thermedics.

10 Referring to Figure 12, an alternate embodiment is shown in which the proximal portion of the inner 26 is axially movable while the distal portion 26b is fixed with respect to the catheter. In between portion 26a and portion 26b is a coil spring 60 inside a flexible sheath 62 of PTFE or the like. Portion 26b of the inner is attached to balloon 14 at the very distal end portion of the catheter. Portion 26a is movable axially 15 within the outer 22. Thus, if 26a is pushed in the distal direction and held to compress coil 60, the coil will enlarge in diameter to provide an enlarged mounting area for a stent. Twisting the inner to twist the coil will enhance enlargement. Alternatively, coil spring 60 may be replaced by a braided element.

20 Also, by providing different pitch over the length of the coil it can be made to enlarge more in some regions than in others. For example, if the coil windings are closer together in the center portions than in the end portions, when the coil undergoes compressing, the two end portions will enlarge in diameter more than the center portion to provide a mount similar to that of Figure 7.

25 Referring now to Figures 13 and 14, another embodiment is shown which is alternative to the earlier described embodiments which are inside the balloon on the catheter. In this embodiment a sheath 80 is carried on the outside of the catheter. Sheath 80 is elastomeric and is axially movable from a stent mounting position as shown in Figure 14 to a position remote from the stent mounting position, such as the retracted position as shown in Figure 13. In the position shown in Figure 13, balloon 14 may be 30 inflated and deflated. In the position shown in Figure 14, balloon 14 will be deflated for low profile. Sheath 80 when over the balloon as in Figure 14 acts to increase the profile

of the catheter to facilitate crimping a stent thereto during deployment of the stent, sheath 80 will expand with balloon 14 to facilitate inflation and during deflation the elastomer sheath will return to its original dimension. An elastomer material which is presently preferred is Tecothane, a trade name for a thermoplastic polyurethane available from

5 Thermedics, Inc., of Woburn, Massachusetts. It may be about 0.003 inches thick, for example.

With respect to Figures 15 and 16, a further embodiment of the invention is shown in which inner 26 carries a mounting body 30, the distal end 100 of which is secured or fixably attached to inner 26, as by any suitable adhesive. The remainder of

10 body 30 is slidable over inner 26 as by the application of compression in the distal direction at the proximal end 102. This may be accomplished by push wire 104 which extends to the proximal end of the catheter for remote manipulation as is known in the art.

Mounting body 30 is accordion folded with more widely spaced folds at

15 the end portions 106, than at the central portion 108. Thus, as can be seen in Figure 15, a relatively low profile is provided without compression for normal angioplasty use. When a stent is to be mounted (not shown), compression by means of push wire 104 will result in a configuration of enlarged diameter of body 30 as shown in Figure 16 to provide a mount similar to that of Figure 7 in general configuration. If the spring is uniform over

20 the body, it will enlarge uniformly, similar to the inner balloon of Figure 11. The Figures are schematic in form but the concept can be readily appreciated.

As an alternative to a folded construction, the body may be of braided construction to achieve the same operation.

Also, this form of body 30 may be inserted into a two piece inner 26

25 similar to the arrangement shown in Figure 12. In all of these arrangements, the accordion folded body material may be of any suitable polymer, such as polyethylene. For example, tubing having a wall thickness of about .002 inches may be used. The accordion folds or pleats may be readily formed in such tubing by means of a pressure mold containing spaced blades placed in a heated chamber.

30 Figures 22-27 show embodiments wherein the inner securement device comprises an inner balloon beneath the outer catheter balloon, similar to above. Figures

22 and 23 illustrate a side profile section showing an inflation expandable stent delivery and deployment assembly generally designated 110. Assembly 110 includes a catheter comprised of inner shafts 112 and 113 and an outer shaft 115 of the coaxial type, an inflation expandable balloon 114, an inflation tube component 116 such as an inner balloon and inflation expandable stent 118. Any conventional type of catheter may be used, such as a catheter of the type generally used for PTA or PTCA angioplasty procedures, for prostate therapy, and TTS endoscopic catheters for gastrointestinal use. However, coaxial types as shown are most preferred. The particular catheter 112 shown is formed of a biocompatible and hydrophilic compatible material, such as a lubricous polyimide or polyethylene. Other suitable materials for the catheter 112 include nylons, urethanes, and polypropylene materials compatible with coatings such as silicone and/or hydrophilic coatings. In addition to hydrophilic compatible materials, any biocompatible material may be used. For example, polyethylene or polypropylene can be coated with a hydrophilic material to render them hydrophilic compatible. Suitable catheters for use according to the present invention include a number of catheters available from SciMed Life Systems, Inc., Maple Grove, Minnesota, the assignee of the present invention, such as BANDIT™, COBRA™, VIVA™, and VIVA PRIMO™ catheters.

Inflatable tube component 116 is fixed at its distal and proximal end to inner shaft 112 and at its proximal end to inner shaft 113 at a position to be encompassed within the distal and proximal ends of the outer balloon 114. According to art-recognized convention, the length L-B of the balloon 114 is defined as the length of the body portion of the balloon 114, excluding the terminal cone sections 120. As seen in Figure 23, the body portion of the balloon 114 is generally cylindrical when in its deployed or inflated condition. Tube component 116 is illustrated as having terminal sections 122 which are more relatively vertical than the cone sections 120 illustrated for the balloon 114. However, it is to be understood that, according to the present invention, either of the terminal sections 120, 122 may be relatively cone shaped, relatively vertical or of any other configuration known to those of skill in this art. A preferred length L-T of the tube component 116 is illustrated in Figures 22 and 23 as substantially equal to the length L-B of balloon 114, and substantially equal to the length L-S of stent 112. However, according to the present invention, stent 112 should be supported by the

underlying tube component 116 for a length sufficient to permit accomplishment of the stated purpose of the tube component 116, when inflated, to provide securement pressure for stent 112 to maintain stent 112 in position with assembly 110 during delivery. It is also within the present invention for tube component 116 to be slightly shorter than stent 5 112, for example, the distal end 119 of stent 112 may extend distally beyond the distal end 121 of tube component 116 (not shown), so that the distal end 119 of stent 121 can be crimped over the distal end 121 of tube component 116 to prevent the distal end 119 of stent 112 from catching and tending to further open as it is maneuvered within a body vessel. As has been explained above, tube component 116 is designed and constructed to 10 be inflatable to no more than is necessary to compensate for recoil crimping of stent 112 and to closely accommodate (or even slightly over-stress) the delivery diameter of stent 112, taking into consideration the thickness of the intervening uninflated balloon 114. Tube component 116 is inflated through the opening(s) 117 of inner shaft 112. Typically, tube component 116 will have a wall thickness of about .0002-.0007 inch and 15 will be inflatable to no more than about .035-.045 inches.

Inflating tube component 116 may be formed of either compliant or non-compliant balloon materials. Compliant materials include low pressure, relatively soft or flexible polymeric materials, such as thermoplastic polymers, thermoplastic elastomers, polyethylene (high density, low density, intermediate density, linear low density), 20 various co-polymers and blends of polyethylene, ionomers, polyesters, polyurethanes, polycarbonates, polyamides, poly-vinyl chloride, acrylonitrile-butadiene-styrene copolymers, polyether-polyester copolymers, and polyetherpolyamide copolymers. Suitable materials include a copolymer polyolefin material available from E.I. DuPont de Nemours and Co. (Wilmington, Del.), under the trade name Surlyn™ Ionomer and a 25 polyether block amide available under the trade name PEBAX™. Non-compliant materials include relatively rigid or stiff high pressure polymeric materials, such as thermoplastic polymers and thermoset polymeric materials, poly(ethylene terephthalate) (commonly referred to as PET), polyimide, thermoplastic polyimide, polyamides, polyesters, polycarbonates, polyphenylene sulfides, polypropylene and rigid 30 polyurethanes.

A balloon 114 for use according to the present invention may be any conventional balloon for catheter delivery, such as a balloon of the type generally used for PTA and PTCA procedures. Typically, balloon 114 is fixed at its distal end to inner shaft 112 near the catheter distal end and at its proximal end to outer shaft 115. Balloon 5 114 is larger in diameter than tube component 116, because balloon 114 must be able to expand to a larger diameter than tube component 116. Balloon 114 is inflatable through an inflation conduit 123, i.e., the space between coaxial inner shaft 113 and outer shaft 115 of the catheter. The distal and proximal ends of balloon 114 are shown in Figures 22 and 23 positioned exterior to the distal and proximal ends of tube component 116, 10 respectively, and of a length L-B generally equal to the length L-T of the tube component 116. To be compatible with tube component 116 illustrated in Figures 22 and 23 and described above, balloon 114 is inflatable at deployment to about the diameter of the body vessel in which the stent 118 is to be deployed. Balloon 114 may be formed of a compliant or non-compliant material, of the types of compliant materials described 15 herein above, such as polyethylene or any standard balloon material. Balloon 114 typically has a wall thickness of about .0007-0.004 inch for example.

A stent for use according to the present invention may be any conventional type of balloon expandable stent, including stents of the type used for PTA and PTCA angioplasty procedures, for prostate therapy, and TTS endoscopic catheters 20 for gastrointestinal use. Suitable stent material is biocompatible stainless steel in the form of sheet metal, tube component wire or Nitinol. A preferred stent is described in PCT Application No. 960 3072 A1, published 8 February 1996, the content of which is incorporated herein by reference. All such stents are well known in this art generally and additional examples are described in U.S. Patent No. 5,507,768 to Lau et al.; in U.S. 25 Patent No. 5,458,615 to Klemm et al; in U.S. Patent No. 5,226,889 to Sheiban; in U.S. Patent No. 4,875,480 to Imbert; in U.S. Patent No. 4,848,343 to Wallsten et al., and in U.S. Patent No. 4,733,665 to Palmaz. Stent 18 as shown in Figures 22 and 23 is positioned on balloon 114, the underlying inflatable tube component 116 and the distal 30 end of the catheter. The length L-S of stent 118 is shown as essentially equal or slightly smaller than the length L-T of tube component 116 and is positioned on assembly 110 to

be co-extensive with tube component 116. In this position, stent 118 is shown in Figure 22 crimped to its delivery diameter D1, which is about .035-.045 inch for example.

As discussed above, despite the most careful and firm crimping of stent 118 to closely conform to the overall profile of the catheter unexpanded balloon 114 and 5 underlying inflatable tube component 116, there is a certain amount of "recoil" of stent 118 or a tendency of stent 118 to slightly open from a desired hypothetical minimum crimped diameter. The actual minimum diameter achievable for fully crimped stent 118 on assembly 110 is referred to as the stent 118 delivery diameter D1. This tendency of 10 stent 118 to open or recoil slightly when crimped on assembly 10 has been characterized as "recoil crimping". In Figure 22, inflatable tube component 116 is shown inflated to a diameter which is generally sufficient to compensate for any slack or looseness between crimped stent 118 and the overall profile of the catheter, the unexpanded balloon 114 and the underlying inflatable tube component 116 due to recoil crimping.

Figure 23 illustrates a side profile section showing a stent delivery and 15 deployment assembly 110 of this invention with balloon 114 fluid inflated to its fully expanded position. As a result of the fluid inflation of the balloon 114, stent 118 has also been fully expanded to its deployment diameter D2 in which it can be deployed against the walls of a body vessel in which it is situated.

Tube component 116 may have a shape other than the cylindrical shape 20 described and illustrated with regard to the embodiment shown in Figures 22 and 23. Further, the tube component may be comprised of more than one separately inflatable pouch. For example, as illustrated with regard to Figure 24, the tube component of an alternative stent delivery and deployment assembly generally designated 130 can be comprised of three separately inflatable pouches 136, 138, 140. The pouches 136, 138, 25 140 are each separately inflatable through their respective inflation conduits 137, 139 141, and each of the pouches 136, 138, 140 can be inflatable to a different extent. The conduits are formed in the wall of shaft 132 as can be seen in Figures 25-27. The stent delivery and deployment assembly 130 of Figure 24 is also comprised of a catheter having inner shaft 132 and outer shaft 135, a balloon 134, with its balloon inflation 30 conduit 139 and the balloon terminal cone sections 144, and a stent 142. As has been explained above with reference to Figures 22 and 23, stent 142 is crimped to closely

conform to the overall profile of the catheter the unexpanded balloon 134 and the underlying inflatable pouches 136, 138, 140. Even with the most careful and firm crimping, there is a certain amount of "recoil" of the stent 142 or a tendency of stent 142 to slightly open from a desired hypothetical minimum diameter. In Figure 24, the first 5 136 and third 140 pouches are inflated to a slightly larger size than the second pouch 138. As discussed above, the inflation of the pouches 136, 138, 140 to this configuration is generally sufficient to compensate for any slack or looseness between the crimped stent 142 and the overall profile of the catheter, the unexpanded balloon 134 and the underlying inflatable pouches 136, 138, 140 due to recoil crimping. Once pouches 136, 10 138 140 have been inflated to the configuration shown in Figure 24, stent 142 is firmly secured against axial movement with regard to assembly 130. The distal 146 and proximal 148 ends of stent 142 are protected from any possible unwanted contact with vessel walls during maneuvering, which helps to protect the vessel walls from abrasion and also helps to protect the ends 146, 148 of stent 142 from distortion. Additionally, 15 stent 142 may be of a length such that it fits over pouch 140 and pouch 136 as well as over pouch 138.

The method of using the stent delivery and deployment assembly 110 of this invention, as shown in Figures 22 and 23, is described as follows. The assembly 110 is constructed as described above. Stent 118 is compressed or crimped onto balloon 114, 20 inflatable tube component 116 and the catheter to a delivery diameter D1. This crimping can be done manually or with the aid of tooling specially designed for the purpose either by the physician or the manufacturer. In the crimped position, stent we closely conforms to the overall profile of balloon 114, inflatable tube component 116 and the catheter except for the slight slack or looseness due to recoil crimping. Tube component 116 is 25 fluid inflated to the extent necessary to compensate for this slack or looseness due to recoil crimping. The pressure of force required to inflate tube component 116 to this extent is also referred to as securement pressure, i.e., the force or pressure needed to secure stent 112 in this position. It is to be noted that, since tube component 116 is designed and constructed to be capable of fully expanding to no more than the size 30 necessary to compensate for recoil crimping, there is no possibility of stent 112 expanding or beginning to open to a larger diameter. Thus, there is no hazard of stent

112 moving out of its position on the catheter during delivery or of becoming separated from the catheter within a body vessel. The catheter distal end is delivered by standard techniques to the deployment site within the body vessel of interest. At this point, stent 112 is positioned as required by the physician and balloon 114 is fluid inflated by 5 standard technique to expand stent 121 to its deployment diameter D2. During this expansion, stent 112 is expanded to fill the body vessel. Following deployment of stent 112, balloon 114 and optionally, tube component 116 are deflated and the assembly 110 is retracted proximally and withdrawn from the body. If required by the procedure, the site of entry to the body is appropriately closed.

10 The method of using the stent delivery and deployment assembly 130 of this invention, as shown in Figure 24, is similarly described. The assembly 130 is constructed as described above. Stent 142 is compressed or crimped to closely conform to the overall profile of balloon 134, inflatable pouches 136, 138, 140 and the catheter except for the slight slack or looseness due to recoil crimping. Pouches 136, 138, 140 are 15 each fluid inflated to the profile shown in Figure 24 through separate fluid inflation conduits (not shown) to securement pressure to compensate for this slack or looseness and to secure stent 142 in this position. The overall configuration of pouches 136, 138 140 further serves to position stent 142 against axial dislocation during delivery. The catheter is delivered by standard techniques to the deployment site within the body vessel 20 of interest. At this point, stent 142 is positioned as required by the physician and balloon 134 is fluid inflated by standard technique to expand and deploy stent 142. Following deployment of stent 142, balloon 134 and, optionally, pouches 136, 138 140 are deflated and the assembly 130 is retracted proximally and withdrawn from the body. If required by the procedure, the site of entry to the body is appropriately closed.

25 The inflation tube component provided by this invention maximizes stent securement force by optimizing the frictional force between the inflating tube component, the balloon wall and the internal diameter of the stent in its reduced crimped delivery diameter. The inflation tube component is more flexible than a solid sheath under the expandable balloon, and thus the entire assembly has greater flexibility. This 30 invention has particular advantages for assemblies in which the stent is provided for use as pre-crimped to the balloon and underlying catheter, by increasing the shelf life of the

pre-crimped assembly. The features and principles described for this invention are suitable for use with fixed wire, over-the-wire and single operator exchange assemblies.

Figures 28-37 disclose still further embodiments of the securement device. Figures 28 and 29 illustrate a side profile section showing an inflation expandable stent delivery and deployment assembly, generally designated 210. Assembly 210 includes a catheter comprised of inner shaft 212 and outer shaft 213 of the coaxial type and an optional retractable delivery shaft 211 (typically called a guide catheter, shown retracted in figure 29, an inflation expandable balloon 214, a corrugated/ribbed stent securement device 216, optional marker bands 217 and an inflation expandable stent 218. Any conventional type of catheter may be used, such as a catheter of the type generally used for PTA or PTCA angioplasty procedures, for prostate therapy, and TTS endoscopic catheters for gastrointestinal use. However, coaxial types as shown are most preferred. The particular catheters 212 and 213 shown are formed of a biocompatible and hydrophilic compatible material, such as a lubricous polyimide or poly ethylene. Other suitable materials for the catheters 212 and 213 include nylons, urethanes, and polypropylene materials compatible with coatings such as silicone and/or hydrophilic coatings. In addition to hydrophilic compatible materials, any biocompatible material may be used. For example, polyethylene or polypropylene can be coated with a hydrophilic material to render them hydrophilic compatible. Suitable catheters for use according to the present invention include a number of catheters available from SciMed Life Systems, Inc., Maple Grove, Minnesota, the assignee of the present invention, such as BANDIT™, COBRA™, VIVA™, VIVA PRIMO™, MAXXUM™, MAXXUM ENERGY™ and RANGER™ catheters.

Securement device 216 is fixed at its distal and/or proximal ends to inner shaft 212 at a position to be encompassed within the distal and proximal ends of the outer balloon 214. According to art-recognized convention, the length L-B of the balloon 214 is defined as the length of the body portion of the balloon 214, excluding the terminal cone sections 220. As seen in figure 29, the body portion of the balloon 214 is generally cylindrical when in its deployed or inflated condition. Securement device/tube component 16 is illustrated as having terminal sections 221,222. It is to be understood that, according to the present invention, either of the terminal sections 220, 222 may be

relatively cone shaped, relatively vertical, relatively flat or of any other configuration known to those of skill in this art. A preferred length L-T of the tubing 216 is illustrated in Figures 28 and 29 as substantially equal to the length L-B of balloon 214, and substantially equal to the length L-S of stent 218. However, according to the present invention, stent 218 should be supported by the underlying tube component 216 for a length sufficient to permit accomplishment of the stated purpose of the tube component 216, to provide a superior securement and protective surface for stent 218 to maintain stent 218 in position with assembly 210 and to protect the balloon material during loading/crimping. It is also within the present invention for the tube component 216 to be slightly shorter than stent 218, for example, the distal end 219 of stent 218 may extend distally beyond the distal end 21 of tube component 216 (not shown), so that the distal end 19 of stent 18 can be crimped over the distal end 221 of tube component 216 to prevent the distal end 221 of stent 218 from catching and tending to snag or further open as it is maneuvered within a body vessel. As has been explained above, tube component 216 is designed and constructed to have enough flexibility and have enough volume to no more than is necessary to compensate for recoil crimping of stent 218 and to closely accommodate (or even slightly over stress) the delivery diameter of stent 218, taking into consideration the thickness of the intervening uninflated balloon 214. Typically, the tube component 216 will have a consistent frequency of ribs, but may also vary by having intermittent groups of ribs along the tubing.

The balloon and the crimped stent slightly conform to the undulations of the tube component for greater securement, but this conformation is not illustrated.

Tube component 216 may be formed from a thermoplastic material, preferably a low modulus polymer, such as Surlyn™, Pebax and urethane. The device such as polypropylene, low density polyethylene (LDPE), high density polyethylene (HDPE), ethylene vinyl acetate (EVA), nylon, polyester and polyethylene terephthalate ("PET"), may be prepared through free blowing in a mold or inside a coil. Tubing is extruded with relatively thin walls and then free-blown in a mold, coil or other fixture to form the ribs/corrugation.

A balloon 214 for use according to the present invention may be any conventional balloon for catheter delivery, such as a balloon of the type generally used

for PTA and PTCA procedures.. Typically, balloon 214 is fixed at its distal end to inner shaft 212 near the catheter distal end and at its proximal end to inner shaft 212, near the distal end of the outer shaft 213. Balloon 214 is inflatable through an inflation conduit 223, i.e., the space between coaxial inner shaft 213 and outer shaft 213 of the catheter.

5 The distal and proximal ends of balloon 214 are shown in Figures 28 and 29 positioned exterior to the distal and proximal ends of tube component 216, respectively, and of a length L-B generally equal to the length L-T of the tube component 216. To be compatible with the tube component 216 illustrated in Figures 28 and 29 and described above, balloon 214 is inflatable at deployment to about the diameter of the body vessel in

10 which the stent 218 is to be deployed. Balloon 214 may be formed of a compliant or non-compliant material, such as polyethylene or any standard balloon material. Compliant materials include low pressure, relatively soft or flexible polymeric materials, such as thermoplastic polymers, thermoplastic elastomers, polyethylene (high density, low density, intermediate density, linear low density), various co-polymers and blends of

15 polyethylene, ionomers, polyesters, polyurethanes, polycarbonates, polyamides, polyvinyl chloride, acrylonitrile-butadiene-styrene copolymers, polyether-polyester copolymers, and polyetherpolyamide copolymers. Suitable materials include a copolymer polyolefin material available from E.I. DuPont de Nemours and Co. (Wilmington, Delaware), under the trade name Surlyn™ Ionomer and a polyether block

20 amide available under the trade name PEBAK™. Non-compliant materials include relatively rigid stiff high pressure polymeric materials, such as thermoplastic polymers and thermoset polymeric materials, poly(ethylene terephthalate) (commonly referred to as PET), polyimide, thermoplastic polyimide, polyamides, polyesters, polycarbonates, polyphenylene sulfides, polypropylene and rigid polyurethanes, or combinations thereof.

25 The balloon 214 typically has a wall thickness of about 0.0007-0.004 inch for example.

A stent for use according to the present invention may be any conventional type of balloon expandable stent, including stents of the type used for PTA and PTCA angioplasty procedures, for prostate therapy, and TTS endoscopic catheters for gastrointestinal use. Suitable stent material is biocompatible stainless steel in the

30 form of sheet metal, tube component wire or Nitinol. A preferred stent is described in PCT Application No. 960 3072 A1, published 8 February 1996, the content of which is

incorporated herein by reference. All such stents are well known in this art generally and additional examples are described in U.S. Patent No. 5,507,768 to Lau et al.; in U.S. Patent No. 5,458,615 to Klemm et al.; in U.S. Patent No. 5,226,899 to Sheiban; in U.S. Patent No. 4,875,480 to Imbert; in U.S. Patent No. 4,848343 to Wallsten et al.; and in 5 U.S. Patent No. 4,733,665 to Palmaz. Stent 218 as shown in Figures 28 and 29 is positioned on balloon 214, which is over the underlying tube component 216, at the distal end of the catheter. The length L-S of stent 218 is shown as essentially equal or slightly smaller than the length L-T of tube component 216 and is positioned on 10 assembly 210 to be coextensive with tube component 216. In this position, stent 218 is shown in Figure 28 crimped to its delivery diameter D1, which is about 0.035-0.45 inch for example.

As discussed above, despite the most careful and firm crimping of stent 218 to closely conform to the overall profile of the catheter unexpanded balloon 214 and underlying tube component 216, there is a certain amount of "recoil" of stent 218 or a 15 tendency of stent 218 to slightly open from a desired hypothetical minimum crimped diameter. The actual minimum diameter achievable for fully crimped stent 218 on assembly 210 is referred to as stent 218 delivery diameter D1. This tendency of stent 218 to open or recoil slightly when crimped on assembly 210 has been characterized as "recoil crimping". In figure 28, tube component 216 is shown inflated to a diameter 20 which is generally sufficient to compensate for any slack or looseness between crimped stent 218 and the overall profile of the catheter, the unexpanded balloon 214 and the underlying tube component 216 due to recoil crimping.

Figure 29 illustrates a side profile section showing a stent delivery and deployment assembly 210 of this invention with balloon 214 fluid inflated to its fully 25 expanded position. As a result of the fluid inflation of the balloon 214, stent 218 has also been fully expanded to its deployment diameter D2 in which it can be deployed against the walls of a body vessel in which it is situated.

Figure 30 illustrates the preferred configuration of the tube component 216. The tube component has a plurality of ribs 230 and is configured in a corrugated or 30 accordion fashion. The ends of the tube component 216, 222 and 221, are substantially rib-free so as to provide a flat surface to receive an adhesive and thereby bond to the

inner shaft 212. Preferable adhesives include cyanocrylates such as Loctite 4061/4011 or urethanes, such as H.B. Fuller 3507/3506. The tube component may also be heat bonded to the inner shaft. The ribs may vary in frequency and spacing.

5       Tube component 216 may have different configurations in other embodiments, as shown in Figures 31-33. The tube component 216 may be comprised of more than one piece of corrugated tubing (Fig. 31), a smaller single piece (Fig. 32) or one single piece of tubing sectioned into a plurality of ribbed sections, wherein the tubing is adhered to the inner shaft 212 in more than two locations (Fig. 33).

10      Figure 31 shows two pieces of tubing component 216a, 216b. Both pieces are adhered to inner shaft 212 at adhesion points 232. Figure 32 discloses an embodiment which comprises one smaller piece of tube component 216 which is adhered to inner shaft 212 at adhesion points 232. Figure 33 discloses an embodiment which comprises one tube component 216 which has interrupted ribbed sections 234 adhered to the inner shaft 212.

15      Figures 34 and 35 illustrate an alternative embodiment in which the tubing component is inflatable to increase the securement pressure on the inside of balloon 214 when the stent is crimped onto the balloon so as to negate additional recoiling. The full expansion of the tube component 216 should only be slightly greater than the diameter of the inside of the balloon 214 when the stent 218 is fully crimped 20 onto the balloon 214.

In Figure 34, the inflating fluid comes through the guide wire lumen 212 under pressure from the proximal end or the distal end of the guide wire lumen 212, preferably via a syringe, and fills the tubing component 216 through a one-way valve 247 (preferably resisting up to about 4 atm) in the inner catheter 212.

25      In figure 35, the tubing component 216 is inflated via an additional lumen 242 which extends from the proximal end of the catheter along the guide wire lumen 240, much the same as any inflating lumen incorporated to inflate a balloon.

30      In an alternative embodiment, as shown in Figure 36, socks or sleeves 251 may be incorporated to stretch over the ends of the stent to prevent snagging and to secure the stent onto the balloon. Such sleeves are demonstrated in U.S. Application

Serial Nos. 08/702,149, filed August 23, 1996, and 08/701,979, filed August 23, 1996, which are incorporated in their entirety herein by reference.

In still another embodiment, as shown in figure 37, the tubing component 216 is slidable axially along the inner shaft 212 and is connected to a retracting wire 250 such that the tubing component may be retracted into the outer shaft 213 after the balloon has been inflated to reduce the profile of the balloon 214 when the catheter is removed. The tubing component, since it is not adhered to the inner shaft 212 in this embodiment, should fit tightly enough on the inner shaft to stay in place, but not too tightly so that it may be retracted by pulling on the retracting wire 250.

10 The method of using the stent delivery and deployment assembly 210 of this invention, as shown in Figures 1 and 2, is described as follows. The assembly 210 is constructed as described above. Stent 218 is compressed or crimped onto balloon 214, tube component 216 and the catheter to a delivery diameter D1. This crimping can be done manually or with the aid of tooling specifically designed for the purpose either by 15 the physician or the manufacturer. In the crimped position, stent 218 closely conforms to the overall profile of balloon 214, tube component 216 and the catheter except for the slight slack or looseness due to recoil crimping. Tube component 216 is flexible enough to slightly collapse during crimping and rebound to the extent necessary to compensate for the slack or looseness due to recoil crimping, thus securing the stent. As a result, the 20 stent does not move out of its position on the catheter during delivery or become separated from the catheter within a body vessel. The catheter distal end is delivered by standard techniques to the deployment site within the body vessel of interest. At this point, stent 218 is positioned as required by the physician and balloon 214 is fluid inflated by standard technique to expand stent 218 to its deployment diameter D2.

25 During this expansion, stent 218 is expanded to fill the body vessel. Following deployment of stent 218, balloon 214 is deflated and the assembly is retracted proximally and withdrawn from the body. If required by the procedure, the site of entry to the body is appropriately closed.

30 The tube component provided by this invention increases stent securement force by increasing the frictional force between the tube component, the balloon wall and the internal diameter of the stent in its reduced crimped delivery diameter. The tube

component is more flexible than a solid sheath under the expandable balloon, and thus the entire assembly has greater flexibility. This invention has particular advantages for assemblies in which the stent is provided for use as pre-crimped to the balloon and underlying catheter, by increasing the shelf life of the pre-crimped assembly. The tube 5 component also protects the balloon material during crimping by acting as a buffer between the balloon material and whatever may be mounted on the inner shaft, such as marker bands 217. The features and principles described for this invention are suitable for use with fixed wire, over-the-wire and single operator exchange assemblies.

Figures 38-46 disclose alternative embodiments of the securement device.

10 Figure 38 shows a stent delivery and deployment assembly generally designated 310. A catheter 312 has a collar 314 coaxially mounted at the catheter distal end portion 316. An uninflated balloon 318 is coaxially mounted on catheter 312 over collar 314. An unexpanded stent 320 is coaxially mounted on the balloon 318 abutting but not overlying collar 314. A cup 322 coaxially overlies the stent proximal end portion 324. Cup 322 15 may be elastomeric or rigid, preferably elastomeric. Cup 322 is over-expanded over the stent 320, so that recoil of the cup 322 is sufficient to secure stent 320 in place and prevent it from being pulled off of the assembly 310 distally or proximally as assembly 310 is delivered to a deployment site in a body vessel. Cup 322 also protects the proximal end of stent 324 from inadvertently catching on anatomical structures or other 20 things during maneuvering within the body or during loading and other handling. The ends of the stent may axially protrude and should be protected during maneuvering of stent 320 to keep stent 20 on assembly 310 in its contracted configuration and to maintain the structural integrity of stent 320. Collar 314 abuts the stent distal end 326 without underlying stent 320. The position of cup 322 overlying stent 320 and 25 containing stent 320 against collar 314 increases the securement force maintaining stent 320 in its axial and radial position on catheter 12. Figure 40 is similar to Figure 38, showing a bulge 28 beneath the uninflated balloon 318 at catheter distal end 316.

Any of the various types of known stents may be used in the delivery system of this invention, even self-expanding stents which are partly balloon-expandable 30 may be used, the balloon initiating release of the stent and/or finally seating the stent

after self-expansion. However, ordinary balloon expandable stents are preferred and aforesaid.

Figure 39 shows another stent delivery and deployment assembly generally designated 330. A catheter 332 has a collar coaxially mounted as a mounting ring 334 on the catheter. An uninflated balloon 338 is coaxially mounted on catheter 332 over mounting ring 334. An unexpanded stent 340 is coaxially mounted on balloon 338 overlying the mounting ring 334. A cup 342 overlies the stent proximal end portion 344 to secure the stent 340 in place and prevent it from being pulled off of assembly 330 distally or proximally, as assembly 330 is delivered to a deployment site in a body vessel. Cup 342 also protects the proximal end of stent 40 from inadvertently catching on anatomical structures during maneuvering within the body. The position of cup 342 overlying stent 340 together with the closer positioning of mounting ring 334 as compared to Figure 38 increases the securement force maintaining stent 340 in its axial and radial position on catheter 342. The closer the mounting ring 334 is positioned to cup 342 the more securely the stent is held in place and interlocked between this cup and ring. When used in conjunction with mounting ring 334, cup 342 will also prevent the stent proximal segment 344 from opening up, i.e., increasing its diameter, and will keep the stent 340 locked onto the mounting ring 334. This will prevent stent 340 from moving on the catheter distally as well as proximally. This cup does not have to be an elastomer, but may be sufficiently rigid to prevent the stent 340 from expanding.

Cups 322, 342 of Figures 38-40 release stents 320, 340 when balloons 318, 338 are inflated during deployment. Cups 322, 342 can, for example, flare radially outward as illustrated with reference to Figure 41, roll axially away from stents 320, 340 as illustrated with reference to Figure 42, or slide axially away from stents 320, 340 as illustrated with reference to Figures 43 and 44. Also, the cups may be formed with axial areas of weakness which split on balloon inflation, as described in the aforesaid Savin patent.

Figure 41 shows an assembly generally designated 310 as shown in Figures 38 and 36 with balloon 318 inflated and stent 320 expanded, showing the cup 322 end portion flared to release stent 320. As noted above, cup 322 may be elastomeric or rigid. The dimension L is short enough and the material of cup 322 is sufficiently

elastic so that cup 322 flares out and is no longer in contact with stent 320 when balloon 318 is inflated and the stent 320 expanded for deployment.

Figure 42 shows an assembly generally designated 310, as shown in Figures 38 and 36, with balloon 318 inflated and stent 320 expanded, showing cup 322 5 end portion rolled proximally to release the stent 320. As noted above, the cup 322 may be elastomeric to facilitate rolling. The cup may also accordion or bunch up on itself to release the stent.

Figures 43 and 44 show yet another stent delivery and deployment 10 assembly generally designated 350. The catheter 352 has a coaxial collar 354 formed integrally with catheter 352 at the catheter distal end 356. A balloon 358 is coaxially mounted on catheter 352, overlying collar 354. In Figure 43, balloon 358 is coaxially mounted on catheter 352, overlying collar 354. In Figure 43, balloon 358 is shown as uninflated, with an unexpanded stent 360 mounted on balloon 358 abutting collar 354, and a cylindrical cup in the form of sleeve 362 overlying the stent proximal end portion 15 364. Figure 44 shows the assembly 350 of Figure 43 with balloon 358 inflated and stent 360 released and expanded. Sleeve 362 is designed, constructed and adapted so that, as balloon 358 and stent 360 are enlarged, the sleeve portion 366 gathers or moves proximally to release stent 360. The increasing angle of the balloon 358 cone (the tapered end sections of balloon 358) during inflation push sleeve 362 axially away from 20 stent 360. This can be done by shaping sleeve 362 with preformed accordion pleats 368. Sleeve 362 may also be formed so that the portion detaining (that is, abutting or overlying) stent 360 is of thicker or more rigid material than the portion of sleeve 362 axially distant from stent 360. Materials which may be used to provide the foregoing 25 function are silicones, urethanes and the like as well as other elastomers, for example. A rigid sleeve carried on the catheter for sliding movement may also be used. Sleeves may be included at the proximal and distal end of the stent.

Figure 45 shows still another stent delivery and deployment assembly 30 generally designated 370. A catheter 372 has two collars 374 formed integrally with catheter 372 and spaced from each other on the catheter distal end portion. A balloon 378 is coaxially mounted on the catheter 372, overlying the collars 374. The balloon 378 is shown as uninflated with an unexpanded stent 380 mounted on balloon 378 abutting

both of the collars 374. It can be seen that the distance between the collars 374 is to be chosen to closely accommodate stent 380 in its fully contracted position about the balloon 378 and underlying catheter 372. A cup 382 overlies the stent proximal end portion 384 and the underlying proximal collar 374. Cup 382 will deploy during balloon 5 378 inflation in the manner described above with reference to Figures 41-44.

Figure 46 shows even another stent delivery and deployment assembly generally designated 390. The uninflated balloon 398 is shown coaxially mounted on a catheter 392 at the catheter distal end portion. An unexpanded stent 400 is coaxially mounted on balloon 398. A pair of cups 402 overlap the ends of the stent 400 ends. A 10 mounting cylinder 404 is carried by the catheter shaft 392.

The Figure also illustrates cups at both ends of the stent, an arrangement which may be used in all the foregoing embodiments.

The cups or sleeves used in the various embodiments of this invention can be of elastomeric or rigid material to contain one or both ends of the stent. In preferred 15 embodiments of this invention the cups are used in conjunction with one or more stent collars positioned under the balloon. The collar may be formed as a ring, to abut the end of the stent, to lie under the stent and the intervening balloon, or as a cylinder, to lie under essentially the entire length of the stent and the intervening balloon. The stent containment according to the present invention offers increased stent securement, 20 particularly on pre-mounted delivery systems. The cups and sleeves illustrated in the various embodiments of this invention can be secured to the catheter, as by adhesive or thermal bonding, or they may be sliding cups or sleeves. When the cups are freely sliding on the catheter, they should always be used directly over a collar so that there is a friction fit between the cup and the stent.

25 A method for delivering and deploying a stent using an assembly according to the present invention is described as follows: A catheter is provided as described above with reference to any of Figures 38-40, 43 and 45. At least one collar is coaxially mounted at the catheter distal end. As discussed above, the collar may be a separate element affixed to the catheter or the collar and catheter may be formed together 30 as a single element. The collar may be positioned abutting an end of the stent. The collar may be a mounting ring, may be positioned under the stent or underlying the

balloon. The collar may be a cylinder essentially coextensive in length with the stent and underlying the balloon. A fluid expandable balloon is coaxially mounted over the collar on the catheter distal end. A stent is provided which is inflation expandable from a reduced to an enlarged condition. The stent, in its reduced condition, is coaxially mounted on the balloon so that at least an end portion of the stent overlies the balloon. A cup is provided which has first and second end portions. The cup is in an expanded form and also has a retracted form. The expanded cup is coaxially mounted on the catheter at the distal end portion so that the cup first end portion detains the stent end portion. The cup first end portion detains the stent end portion by overlying the stent end portion, or by closely accommodating the stent against the collar without overlying the stent end portion. The cup is then contracted about the catheter and the stent end portion to fix the stent to the catheter. The cup and collar cooperate to retain the stent on the catheter in its reduced condition. The assembly is then maneuvered by the physician through a body vessel by methods known *per se* to reach a pre-selected deployment site. The surgeon can determine when the assembly has reached the deployment site by means which are themselves known *per se*. For example, the assembly may be provided with radiopaque marking bands at either end of the stent, or the cups or the collars or both may be made of radiopaque material. Once the surgeon determines that the stent has been correctly positioned at the desired site, the balloon is inflated to expand the stent to its enlarged condition. Inflation of the balloon expands the stent and the stent is released from the cup or cups. As has been discussed above, the cups may deploy to release the stent in a number of ways, dependant on the construction and materials of the cup or cups. The cup may flare or enlarge radially following the increasing angle of the balloon cones. The cup may roll axially away from the stent. The portion of the cup axially distant from the stent may accordion back on itself. The cup may slide axially. The cup may accordion or buckle. If the cup is not fixed to the catheter, but is freely slidable on the catheter, the cup may slide axially away from the stent. After deployment of the stent, the balloon, according to previously known procedures, is deflated and the assembly is withdrawn proximally from the body vessel. Any incision made to allow access from the assembly is appropriately closed.

Figures 47-56 illustrated alternative embodiments of securement devices.

Referring to Figures 47 and 48 a stent delivery system generally indicated at 410 includes a balloon catheter 412 having a balloon 414 on a distal end portion generally indicated at 416. Figure 47 shows a proximal portion of the catheter at 412a and a distal portion 412b in enlarged view. Figure 48 shows the distal end portion 416 in an even more enlarged view. The illustrative catheter 412 is of the type known as an over the wire catheter. However, other types of catheters may be used, such as rapid exchange/single operator exchange and fixed wire types. The balloon 414 is fixed to the catheter 412 by standard means. The balloon is shown in its contracted state in Figures 5 47 and 48. A stent 418 is fixed about the balloon by crimping it thereto. The stent has a larger expanded diameter which is obtained when the balloon is expanded in the known manner. That is, the stent is released from the catheter upon expansion of the balloon when placed in a vessel. When the balloon is then deflated, removal of the balloon and catheter may be accomplished while leaving the stent in place.

10 15 As is known in the art the balloon is either bonded at its ends by adhesive 420 and 422, respectively to the outer member 424 of the catheter and to the inner member 426 of the catheter in the manner as shown, or is made one-piece with the outer member as is known in the art. The catheter balloon may be inflated by fluid (gas or liquid) from an inflation port extending from a lumen 428 contained in the catheter shaft 20 and opening into the balloon as shown, or by other known arrangements, depending on the design of the catheter. The details and mechanics of balloon inflation and specific overall catheter construction will vary according to the particular design involved in any given instance, and are known in the art *per se*. All variations are acceptable for use with this invention.

25 Any balloon expandable stent may be used with this invention. Many are known in the art including plastic and metal stents. Some are more well known such as the stainless steel stent shown in U.S. Patent No. 4,735,665; the wire stent shown in U.S. Patent No. 4,950,227; another metal stent shown in European Patent Application No. EP0 707 837 A1 and that shown in U.S. Patent No. 5,445,646. All of these patents are 30 incorporated herein by reference. Also, shape memory metal stents may be used. As already indicated the stent of PCT Application 960 3092 A1 is particularly preferred.

The stent is typically about 16mm long, while the balloon may be 20 mm long. These dimensions, however, are merely representative for illustrative purposes only and are not meant to be limiting. The stent is positioned over the balloon portion of the dilatation catheter and gently crimped onto the balloon either by hand or with a tool such as a pliers or the like to be mounted for delivery as shown in Figures 47 and 48.

5 The crimping may be accomplished by either the manufacturer or the physician.

In accordance with one embodiment of this invention, a mounting bodies 430, seen in Figures 47 and 48 are included inside balloon 414 to provide a cushion and/or substrate of enlarged diameter relative to the shaft to support and hold the stent 10 and secure it during crimping and the delivery procedure. The mounting bodies are preferably located in the body portion of the balloon.

In the embodiment shown, mounting bodies 430 are ring-like in form and are mounted on inner lumen 426, providing an enlarged area or portion for receiving the balloon and stent when the latter is crimped. Marker bands 432 and 434 may also be 15 included on inner 426 as shown. Any radiopaque material such as gold is useful for this purpose. Although, the material of the mounting bodies may be hard, it is preferably of any thermoplastic elastomer having elastic or deformable properties, more preferably of a relatively resilient elastomer material, e.g., silicone, preferably a lower durometer silicone, or polyurethane, such as Tecothane 1055D. A deformable thermoplastic 20 material such as high density polyethylene (HDPE) may be used. Any deformation of resilient material of the mounting body when the stent/balloon is crimped to it causes a radial outward force on the stent/balloon increasing the friction therebetween despite a recoil of the stent.

The stent is also fixed in position by two overlying retaining sleeves 436 25 and 438. Sleeves 436 and 438 are formed of polyurethane, preferably Tecothane 1055D, and are axially fixed on catheter 412 by adhesive plugs 440 and 442 of urethane adhesive. The plugs of adhesive may be tapered to the catheter as shown to facilitate movement of the catheter in a vessel. The sleeves overlap the marginal end portions of stent 418 as shown.

A lubricating solution such as silicone fluid may be used between balloon 414 and sleeves 436 and 438 and thereon to facilitate release of stent 418 from the sleeves.

During delivery, the balloon catheter is advanced through and positioned 5 in a patient's vasculature so that the stent is adjacent to the portion of the vessel where treatment is to take place. The balloon is inflated to expand the stent to an enlarged diameter. At this time, expansion of the balloon causes the end margin of the sleeves to slide axially from over the stent thereby releasing the ends of the stent from the catheter. Various forms of retraction of sleeves 436 and 438 are shown in Figures 49-52. These 10 figures illustrate the configuration of the sleeves 436 and 438 in their retracted state after the balloon 414 has been fully expanded. Only the distal sleeve 438 is shown. Figure 49 illustrates the preferably retraction configuration. To promote easier retraction sleeves are coated with silicone. The sleeves are preferably adhered to the outer shaft 424 and the inner shaft 426 at point 440, 442, but may be adhered further up the waste 441 of the 15 balloon. The retraction configurations may be controlled by either pre-creasing the sleeves or adhering the sleeve to a point further up on the waist of the balloon. The sleeves have a tendency of folding at a pre-fold crease or at the point of adherence. A preferred cone angle of 45° for the balloon is shown in Figure 52, which shows an expanded balloon 414 and retracted sleeves 436,438. When the stent has reached the 20 desired diameter, the balloon is deflated so that the catheter may be removed leaving the stent in place.

A modified 439 sleeve configuration is shown in Figure 53 in stepped form 43 having a large diameter at 444 in one section 446 and a small diameter 445 in a second section 450.

25 Figures 54-56 show alternative embodiments of the invention. Specifically, alternative positioning and number of mounting bodies 430. These figures show an unexpanded balloon having the mounted bodies 430 within the balloon. They are meant to illustrate essentially the same structure as shown in Figure 448 differing only in the number and positioning of the mounted bodies 430. In the embodiment 30 shown in Figure 54, the ring-like mounting body 430 is singular. Another similar version

is shown in Figure 55 which includes three ring-like mounting bodies 430. The embodiment shown in Figure 56 includes four ring-like mounting bodies 430.

It should be understood that the various elements and materials of all embodiments could be utilized in each of the other embodiments, if desired.

5 The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which 10 equivalents are also intended to be encompassed by the claims attached hereto.

## CLAIMS

**What is claimed is:**

1. A system/assembly for delivery and deployment of an inflation expandable stent within a vessel, comprising:
  - 5 a catheter having proximal and distal ends;
  - a stent, inflation expandable from a delivery diameter to a deployment diameter, such that the delivery diameter is reduced from the deployment diameter for conforming the stent to the catheter, such that the stent, in its delivery diameter, is coaxially mounted
  - 10 on the catheter near the catheter distal end;  
an expandable inflation means coaxially mounted on the catheter axially within the stent, for expansion of the stent from the delivery diameter to the deployment diameter upon application of fluid deployment pressure to the inflation means; and  
a securement component coaxially mounted on the catheter, axially within the
  - 15 expandable inflation means, the securement component designed and adapted to provide a securement pressure to the stent in the delivery diameter to maintain the stent in position on the catheter during delivery to the deployment site.
2. The system of claim 1, the catheter having a shaft and the expandable inflatable means associated therewith at a distal part of the shaft and including mounting
- 20 and retaining means for receiving the stent on the expandable means for radial expansion of the stent, the mounting and retaining means being associated with the inflatable means and being constructed and arranged for selectively providing an enlarged mounting body for receiving the stent.
3. The system of claim 2 wherein the mounting body is inside the inflatable
- 25 means.
4. The system of claim 2 wherein the mounting body is outside the inflatable means.
5. The system of claim 2, the inflatable means being a balloon, wherein the
- 30 mounting body is carried by the catheter and is axially movable between the stent mounting position associated with the balloon and a position removed from the stent mounting position.

6. The system of claim 1, the catheter having a shaft, the expandable inflatable means being associated therewith at a distal part of the shaft and including mounting and retaining means for receiving a stent on the expandable inflatable means and for radial expansion of the stent upon inflation of the inflatable means, the mounting and retaining means including at least one mounting body carried on and surrounding the shaft inside the inflatable means whereby the diameter of the shaft and inflatable portion may be increased at the distal part of the shaft for facilitating the mounting and retaining of the stent.  
5
7. The delivery system of claim 6 wherein the mounting body is axially movable with respect to the inside shaft, and including means for moving the mounting body.  
10
8. The stent delivery system of claim 7 wherein the mounting body is of a material which resiliently deforms under radial pressure.  
15
9. The stent delivery system of claim 8 wherein the material comprises HDPE or silicone.  
15
10. The stent delivery system of claim 7 wherein the mounting body configuration includes at least one separation whereby the flexibility of the body and catheter is increased.  
20
11. The stent delivery system of claim 10 wherein the separation is in the form of a spiral.  
20
12. The stent delivery system of claim 7 wherein the mounting body is positionable to receive a stent and a stent is crimped to the mounting and retaining means over the balloon for delivery.  
25
13. The stent delivery system of claim 6 including a stop positioned at the distal end portion of the inflatable means and carried by the shaft inside the inflatable means.  
25
14. The stent delivery system of claim 6 including at least one marker band.  
15
15. The stent delivery system of claim 6 wherein the inflatable means comprises a balloon.  
30
16. The stent delivery system of claim 6 including a stop positioned at the distal end of the catheter and carried by the shaft inside the inflatable means.  
30

17. The stent delivery system of claim 6 wherein the mounting body is in a fixed position and is adapted and arranged to enlarge in diameter to receive a stent.
18. The stent delivery system of claim 17 wherein the mounting body is a second inflatable means inside the first inflatable means, the inner one being shaped to have wide end portions and a narrow center portion.
19. The stent delivery system of claim 17 wherein the mounting body is a coil-like structure adapted and arranged to be compressed and the proximal portion of the inside shaft is connected thereto for compressing the structure to enlarge its diameter.
20. The system of claim 17 wherein the mounting body is a sleeve including radial accordion like pleats extending over at least a portion of its length, the distal end being secured to the inside shaft and a means for compressing the body from its proximal end and attached thereto.
21. The system of claim 20 wherein the pleats of certain portions of the body are spaced differently to provide regions of different enlargement.
22. The stent delivery system of claim 19 wherein the coil is coated with a polymer.
23. The stent delivery system of claim 29 wherein the coil is enclosed in a polymeric sheath.
24. The stent delivery system of claim 7 wherein the mounting body is a slidably carried coil.
25. The system of claim 1, the inflation means being a balloon, and further including an elastomeric sheath carried over the balloon, the sheath being constructed and arranged for axial movement and positioning between a stent mounting position over the balloon and a position removed from the stent mounting position.
26. A method of changing the profile of a balloon catheter for improving the mounting of a stent thereon and providing a catheter for multiple use, comprising the steps of:
  - providing a balloon catheter of relatively low profile adapted and rearranged for use in an angioplasty procedure;
  - sliding a stent mounting body to a position associated with the balloon to a position for receiving a stent and enlarging the catheter profile at that position, and

mounting a stent on the balloon and mounting body at that position.

27. In a balloon catheter apparatus, the method of enlarging the catheter profile for facilitating the mounting of a stent thereon, comprising:

selectively providing an enlarged mounting body within the balloon in a position  
5 to receive a stent.

28. The method of claim 27 wherein the enlarged body is provided by sliding it into the position.

29. The method of claim 27 wherein the enlarged body is provided by inflating an inner balloon within the catheter balloon.

10 30. The method of claim 27 wherein the enlarged body is provided by compressing a body already in the position to enlarge its diameter for receiving a stent.

15 31. The assembly of claim, the inflatable means being an expandable balloon coaxially mounted on the catheter axially within the stent, for expansion of the stent from the delivery diameter to the deployment diameter upon application of fluid deployment pressure to the balloon; and the securement component being an expandable tube component coaxially mounted on the catheter, axially within the expandable balloon, the tube component designed and adapted for fluid expansion to provide a securement pressure to the stent in the delivery diameter to maintain the stent in position on the catheter during delivery to the deployment site.

20 32. The assembly according to claim 31, wherein the expandable tube component is sized and constructed to be fluid expandable to no more than the delivery diameter and to no more than the securement pressure.

25 33. The assembly according to claim 31, wherein the tube component is essentially equal in length to the stent and wherein the stent is positioned on the assembly essentially coextensive with the tube component.

34. The assembly according to claim 32, wherein the tube component is comprised of more than one inflatable pouch.

30 35. The assembly according to claim 34, wherein the tube component is comprised of three pouches, with a proximal and distal pouch inflatable to a greater pressure than a medial pouch.

36. A method for delivering and deploying a stent using an assembly according to claim 31, comprising:

providing a catheter having proximal and distal ends, with an expandable balloon coaxially mounted on the catheter, and an expandable tube component coaxially mounted 5 on the catheter, axially within the expandable balloon, so that the balloon and the tube component are each in an unexpanded condition;

providing a stent which is expandable from a delivery diameter to a deployment diameter;

mounting the stent, in a diameter greater than the delivery diameter, on the 10 balloon;

contracting the stent to the delivery diameter to conform to an overall profile of the catheter, the tube component and the balloon;

inflating the tube component to provide to the stent a securement pressure to retain the stent in the delivery diameter;

15 delivering the assembly to a deployment site; and

inflating the balloon to expand the stent to its deployment diameter.

37. The method according to claim 36, wherein the expandable tube component is sized and constructed to be fluid expandable to no more than the delivery diameter.

20 38. The method according to claim 36, wherein the tube component is essentially equal in length to the stent and wherein the stent is positioned on the assembly essentially coextensive with the tube component.

39. The method according to claim 36, wherein the tube component is comprised of more than one inflatable pouch.

25 40. The method according to claim 39, wherein the tube component is comprised of three pouches, with a proximal and distal pouch inflatable to a greater pressure than a medial pouch.

41. The assembly according to claim 1, the catheter having an inner shaft, the 30 inflatable means being an expandable balloon coaxially mounted on the catheter axially; and the securement component comprising a tube component coaxially mounted on the

catheter axially within the expandable balloon, the tube component having a plurality of ribs.

42. The assembly according to claim 41, further comprising a stent, inflation expandable from a delivery diameter to a deployment diameter, such that the delivery 5 diameter is reduced from the deployment diameter for conforming the stent to the catheter, such that the stent, in its delivery diameter, is coaxially mounted on the catheter near the catheter distal end, the expandable balloon being capable of expansion of the stent from the delivery diameter to the deployment diameter upon application of fluid deployment pressure to the balloon.

10 43. The assembly according to claim 42, the catheter comprising an inner shaft and an outer shaft, wherein the tube component is a thermoplastic corrugated tube adhered to the inner shaft and is formed from a low modulus polymer.

15 44. The assembly according to claim 43, the tube component being formed from a material chosen from the group consisting of polypropylene, low density polyethylene (LDPE), high density polyethylene (HDPE), ethylene vinyl acetate (EVA), nylon, polyester, polyethylene terephthalate ("PET"), Surlyn™, Pebax and urethane

45. The assembly according to claim 43, wherein the diameter of the tube component is approximately equal to the delivery diameter of the stent.

20 46. The assembly according to claim 45, wherein the tube component is essentially equal in length to the stent and wherein the stent is positioned on the assembly essentially coextensive with the tube component.

47. The assembly according to claim 42, wherein the tube component is comprised of more than one corrugated tube.

25 48. The assembly according to claim 46, further comprising marker bands fixed to the inner shaft beneath the tube component.

49. The assembly according to claim 42, wherein the tube component is inflatable, such that when the tube component is inflated it applies radial pressure on the expandable balloon, when the stent is in its delivery diameter.

30 50. The assembly according to claim 42, further comprising at least one sleeve having first and second ends, the first end being attached to the catheter and the second end covering a portion of the stent, when the stent is in its delivery diameter.

51. The assembly according to claim 50, comprising two sleeves, one covering each end of the stent, when the stent is in its delivery diameter.

52. The assembly according to claim 42, wherein the tube component is 5 slideable along the inner shaft and is attached to a retracting means, such that after the stent has been deployed, the user may slide the tube component proximally along the inner shaft.

53. A method for delivering and deploying a stent using an assembly according to claim 41, comprising:

10 providing a catheter having proximal and distal ends, with an expandable balloon coaxially mounted on the catheter, and a tube component having a plurality of ribs coaxially mounted on the catheter, axially within the expandable balloon, so that the balloon is in an unexpanded condition;

providing a stent which is expandable from a delivery diameter to a deployment diameter;

15 mounting the stent, in a diameter greater than the delivery diameter, on the balloon;

contracting the stent to the delivery diameter to conform to an overall profile of the catheter, the tube component and the balloon;

delivering the assembly to a deployment site; and

20 inflating the balloon to expand the stent to its deployment diameter.

54. The method according to claim 53, wherein the tube component is a corrugate tubing adhered to the catheter formed of a low modulus polymer and having a diameter of approximately that of the delivery diameter.

55. The assembly of claim 1, the inflatable means comprising an expandable 25 balloon, further comprising an annular collar coaxially located at the catheter distal end portion, the expandable balloon coaxially mounted over the collar at the catheter distal end portion, the balloon being expandable from a contracted to an expanded state, the stent coaxially mounted on the balloon, the reduced condition conforming the stent to the balloon, collar and catheter, the stent having at least an end portion overlying the balloon, 30 the system further comprising a cup coaxially mounted on the catheter distal end portion, the cup having a first end portion restraining the stent end portion and the cup and collar

cooperatively constructed and arranged to retain the stent end portion on the catheter in the stent reduced condition when the balloon is in the contracted state, the balloon and catheter cooperatively constructed and arranged to cause expansion of the balloon from the contracted to the expanded state and to release the stent end portion from the cup end portion.

5 56. The assembly according to claim 55, wherein the cup is axially spaced from the collar.

57. The assembly according to claim 55, wherein the cup has a second end portion fixed to the catheter.

10 58. The assembly according to claim 55, wherein the cup first end portion overlies the stent end portion.

59. The assembly according to claim 55, wherein the cup is elastomeric.

60. The assembly according to claim 55, wherein the cup is rigid.

15 61. The assembly according to claim 57, wherein the second end portion is fixed with adhesive.

62. The assembly according to claim 55, wherein the collar is formed as a single member with the catheter.

20 63. The assembly according to claim 55, wherein the stent end portion is a distal end portion and wherein the cup and collar cooperate to retain the stent at the stent distal end portion.

64. The assembly according to claim 55, wherein the collar is axially positioned exterior to the stent at a stent end portion opposite the stent end portion retained by the cup.

25 65. The assembly according to claim 64 wherein the collar is formed as a single member with the catheter.

66. The assembly according to claim 55, wherein the collar is a mounting ring axially positioned between stent end portions.

67. The assembly according to claim 66, wherein the mounting ring is formed as a single member with the catheter.

30 68. The assembly according to claim 66, wherein at least a portion of the mounting ring is contained by the cup.

69. The assembly according to claim 55, wherein the collar is a cylinder under the stent.
70. The assembly according to claim 69, wherein at least a portion of the cylinder is contained by the cup.
- 5 71. The assembly according to claim 69, wherein the cylinder is formed as a single member with the catheter.
72. The assembly according to claim 55, wherein a second collar is a mounting ring axially positioned between stent end portions.
- 10 73. The assembly according to claim 55, wherein a second collar is axially positioned immediately exterior to the stent at a stent end portion opposite the stent end portion retained by the cup.
74. The assembly according to claim 55, wherein the cup and the collar are each cylindrical.
- 15 75. The assembly according to claim 55, wherein the cup has a second end portion with axially running regions of weakness.
76. The assembly according to claim 55, and further including a second cup coaxially mounted on the catheter at the catheter distal end, the second cup having a first end portion overlying a stent second end portion;  
the cups and the collar cooperatively constructed and arranged to retain the  
20 respective stent end portions on the catheter in the stent reduced condition when the balloon is in the contracted state, the balloon and catheter cooperatively constructed and arranged to cause expansion of the balloon from the contracted to the expanded state to cause release of the stent end portions from the cup end portions.
77. The assembly according to claim 76, wherein the cups are elastomeric.
- 25 78. The assembly according to claim 76, wherein the cups are rigid.
79. The assembly according to claim 76, wherein the collar is formed as a single member with the catheter.
80. The assembly according to claim 76, wherein the collar is axially positioned immediately exterior to the stent at a stent end portion opposite the stent end  
30 portion retained by the cup.

81. The assembly according to claim 80, wherein the collar is shaped as a single member with the catheter.
82. The assembly according to claim 76, wherein the collar is a mounting ring axially positioned between stent end portions.
- 5 83. The assembly according to claim 82, wherein the mounting ring is shaped as a single member with the catheter.
84. The assembly according to claim 82, wherein at least a portion of the mounting ring is contained by a cup.
- 10 85. The assembly according to claim 76, wherein the collar is a cylinder coextensive with the length of the stent.
86. The assembly according to claim 85, wherein the cylinder is formed as a single member with the catheter.
87. The assembly according to claim 85, wherein at least a portion of the cylinder is contained by a cup.
- 15 88. The assembly according to claim 87, wherein each cup contains at least a portion of the cylinder.
89. The assembly according to claim 76, wherein a second collar is a mounting ring axially positioned between stent end portions.
90. The assembly according to claim 76, wherein a second collar is axially positioned immediately exterior to the stent at a stent end portion opposite the stent end portion retained by the cup.
- 20 91. The assembly according to claim 76, and further comprising fixing means for holding the collar at a specific location on the catheter, wherein the fixing means is adhesive.
- 25 92. A method for delivering and deploying a stent using the assembly of claim 55, comprising:
  - providing a catheter having proximal and distal ends, with a collar coaxially mounted at the catheter distal end, and a fluid expandable balloon coaxially mounted over the collar on the catheter distal end,
  - 30 providing a stent being expandable from a reduced to an enlarged condition;

mounting the stent in the reduced condition coaxially on the balloon, so that an end portion of the stent overlies the balloon;

providing a cup having first and second end portions, the cup being in an expanded form, and also having a retracted form;

5 mounting the expanded cup coaxially on the catheter distal end, so that the cup first end portion overlies the stent end portion;

contracting the cup about the catheter and the stent end portion to fix the stent to the catheter, the cup and collar cooperating to retain the stent in the reduced condition, delivering the assembly to a deployment site; and

10 inflating the balloon to release the stent from the cup.

93. The assembly according to claim 1, the securement component comprising a mounting body carried by the catheter at the distal end portion, the inflatable means comprising an expandable balloon coaxially mounted over the catheter distal end and the mounting body, the balloon being expandable from a contracted to an 15 expanded state, the stent having an end portion overlying the balloon, the assembly comprising:

first and second cups coaxially mounted on the catheter distal end, each cup having a first end portion overlying a stent end portion, respectively; and

20 the cups constructed and arranged to retain the stent therebetween on the catheter in the stent reduced condition when the balloon is in the contracted state, the balloon and catheter cooperatively constructed and arranged to cause expansion of the balloon from the contracted to the expanded state to cause expansion of the stent, including the stent end portions, from the reduced to the enlarged condition, and thereby release the stent from abutting the cup end portions.

25 94. A method for delivering and deploying a stent using the assembly of claim 93, comprising:

providing a catheter having proximal and distal ends and a fluid expandable balloon coaxially mounted over the collar on the catheter distal end;

30 providing a stent being inflation expandable from a reduced to an enlarged condition;

mounting the stent in the reduced condition coaxially on the balloon so that an end portion of the stent overlies the balloon;

providing first and second cups each having first and second end portions, the cups being in an expanded form and also having a retracted form;

5        mounting the expanded cups coaxially on the catheter distal end so that the cup first end portions overlie the stent end portions;

contracting the cups about the catheter and the stent end portions to fix the stent to the catheter, the cups cooperating to retain the stent in the reduced condition;

delivering the assembly to a deployment site; and

10        inflating the balloon to expand the stent to its enlarged condition, whereby the stent is released from the cups.

95.        The system according to claim 1, the catheter having a shaft and the inflatable/expandable means being associated therewith at a distal part of the shaft, the securement component comprising mounting and retaining means for receiving the stent on the expandable means for radial expansion of the stent upon expansion of the expandable means, the mounting and retaining means including at least one mounting body carried on the shaft inside the inflatable means whereby the diameter of the shaft and expandable means are increased at the distal part for facilitating the mounting and retaining of the stent, and further including

20        a sleeve at the distal portion of the catheter, having a first end fixed to the catheter and a second end overlying an end portion of the stent, the sleeve sliding axially to release the stent upon expansion of the expandable means.

96.        The stent delivery system of claim 95 wherein the mounting body is of a material which resiliently deforms under radial pressure.

25        97.        The stent delivery system of claim 96 wherein the material is elastomeric.

98.        The stent delivery system of claim 96 wherein the material comprises polyurethane.

99.        The stent delivery system of claim 95 wherein the stent is crimped to the mounting and retaining means for delivery.

30        100.        The stent delivery system of claim 95 including marker bands positioned on the shaft proximally and distally of the stent.

101. The stent delivery system of claim 95 wherein the expandable means comprises a balloon.

102. The stent delivery system of claim 1, the catheter having a shaft and the inflatable/expandable means associated therewith at a distal part of the shaft, the 5  
securement component including mounting and retaining means for receiving the stent to be delivered upon expansion of the inflatable means, the mounting and retaining means including at least one ring-like body inside the expandable means and carried by the shaft, and the stent crimped to the expandable means and the mounting body such that the stent is carried on the shaft and mounting body until expansion of the stent and 10  
expandable means, the system further comprising a first and second sleeve in the distal part of the catheter positioned around the catheter, each having a first end fixed to the catheter and a second end overlying first and second end portions of the stent respectively, the first and second sleeves separately fixing the stent before expansion thereof and upon expansion of the expandable means and stent releasing the stent by 15  
sliding axially from over the stent.

103. The stent delivery system of claim 102 wherein the stent is generally tubular in shape and the mounting body is generally ring-like in shape.

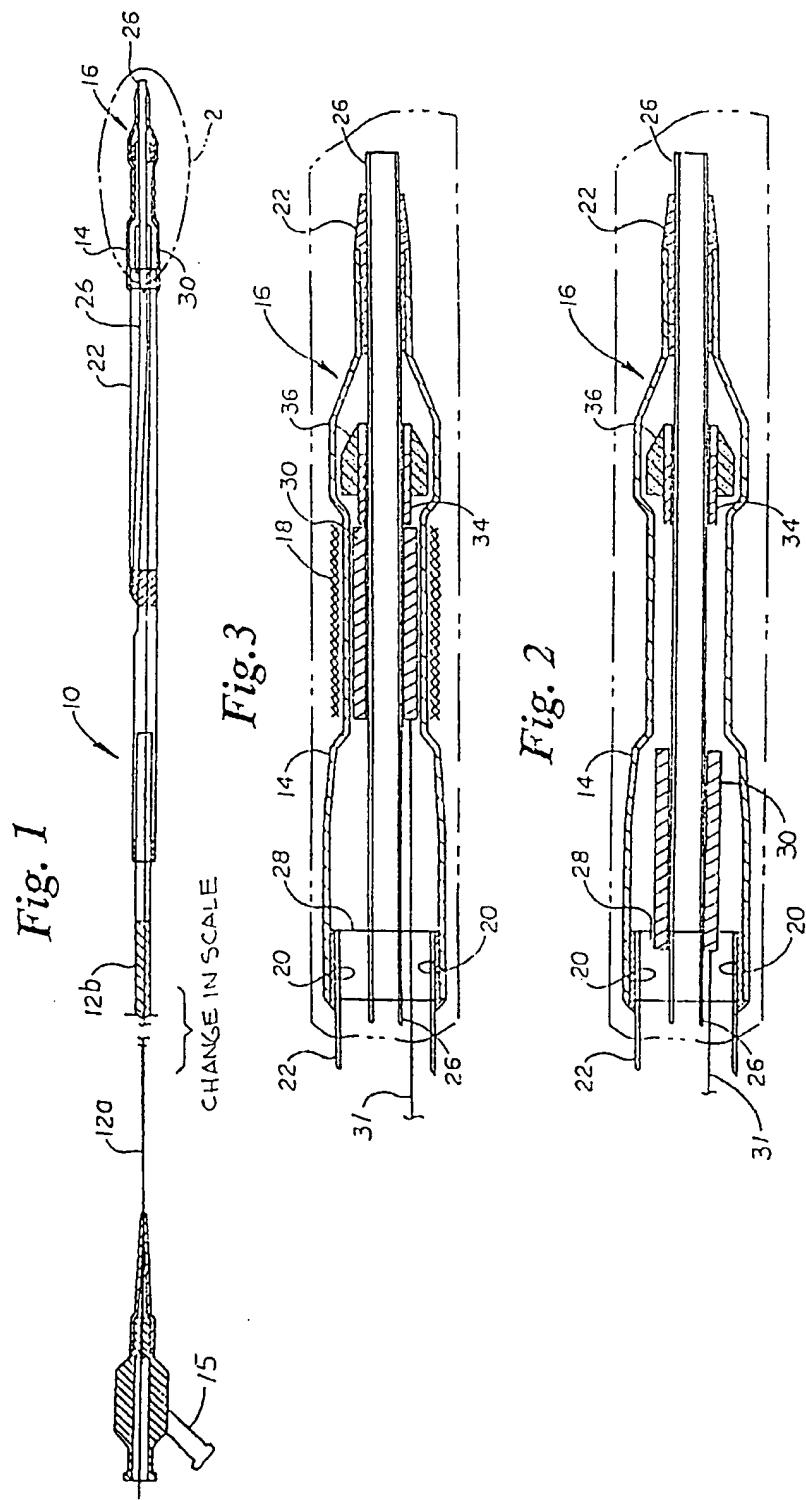
104. The stent delivery system of claim 102 wherein at least two spaced mounting bodies are included.

20 105. The stent delivery system of claim 102 wherein at least three spaced mounting bodies are included.

106. The stent delivery system of claim 102 wherein at least four spaced mounting bodies are included.

107. The system according to claim 1, the catheter comprising a shaft, the 25  
inflatable means comprising a balloon associated with a distal portion of the shaft for receiving a stent, and means for inflating the balloon, the securement component including at least one ring-like mounting body carried on the shaft inside the balloon whereby the diameter of the shaft is increased inside the balloon to facilitate mounting of a stent to the catheter over the balloon and further including, the system further 30  
comprising a first and second sleeve in the distal part of the catheter positioned around the catheter, each having a first end fixed to the catheter and a second end overlying first

and second end portions of the stent respectively, the first and second sleeves separately fixing the stent before expansion thereof and upon expansion of the expandable means and stent releasing the stent by sliding axially from over the stent.



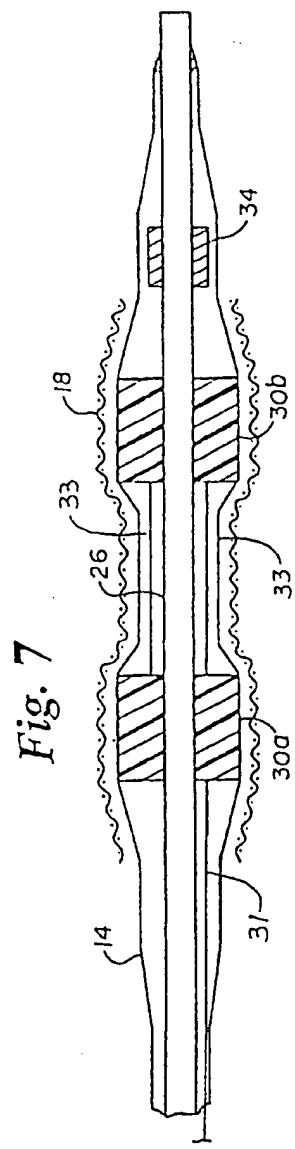
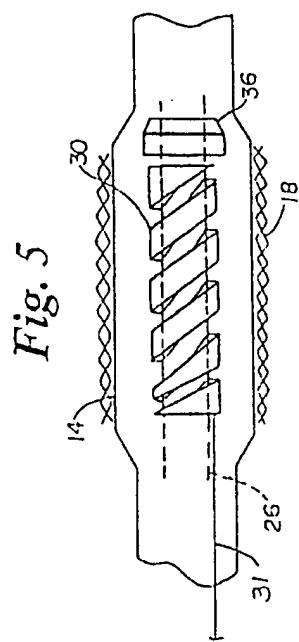
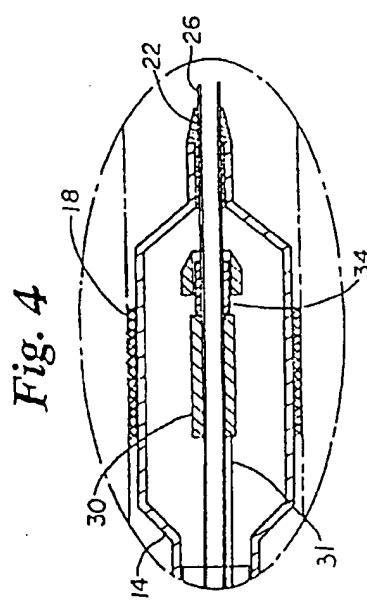
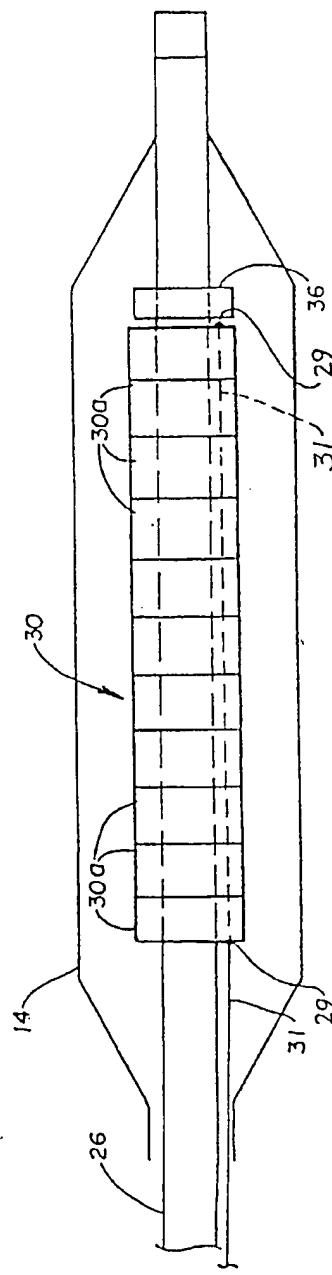


Fig. 6



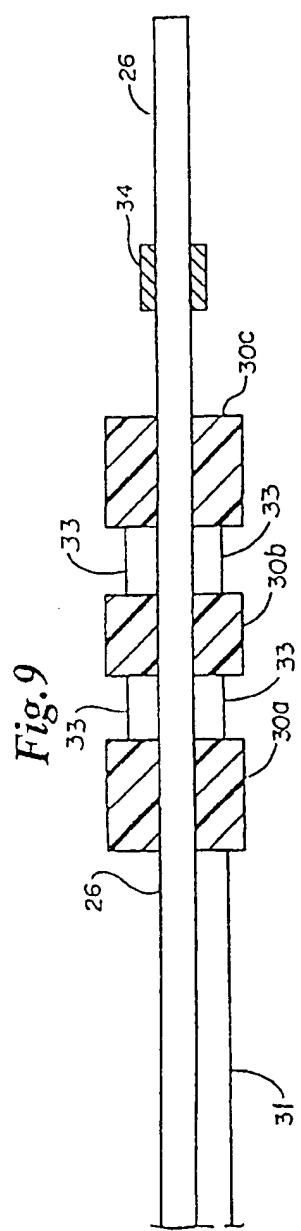
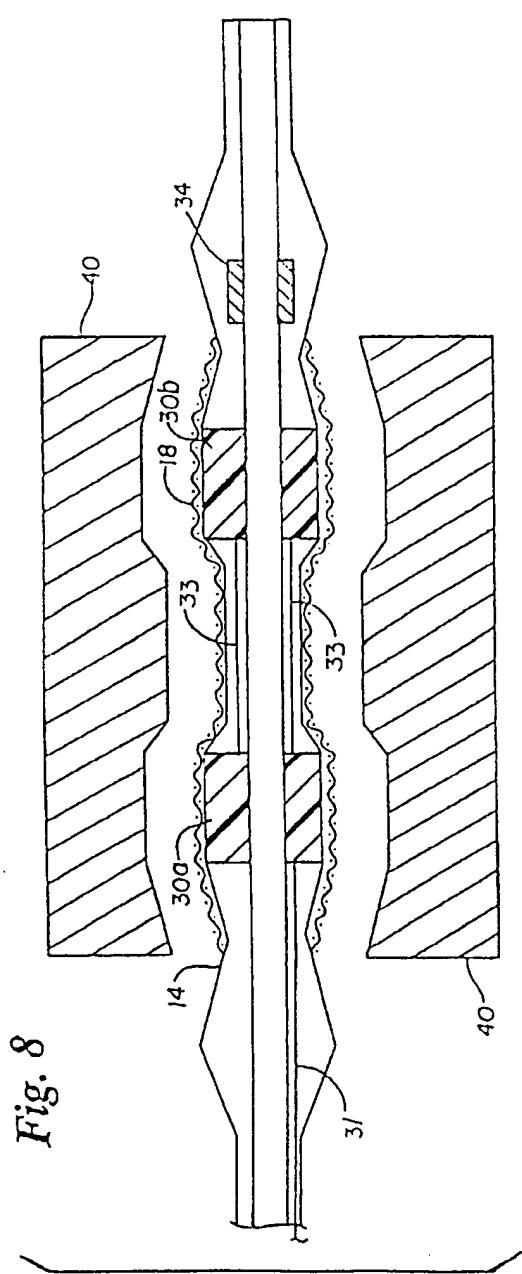


Fig.10

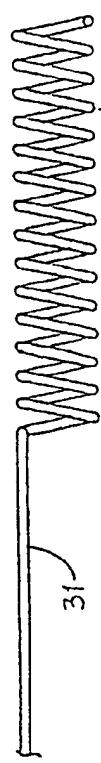


Fig.11

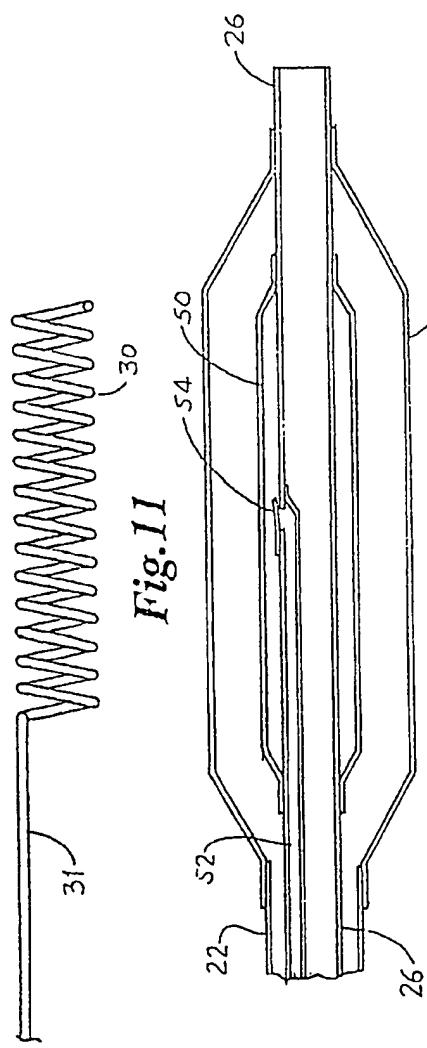
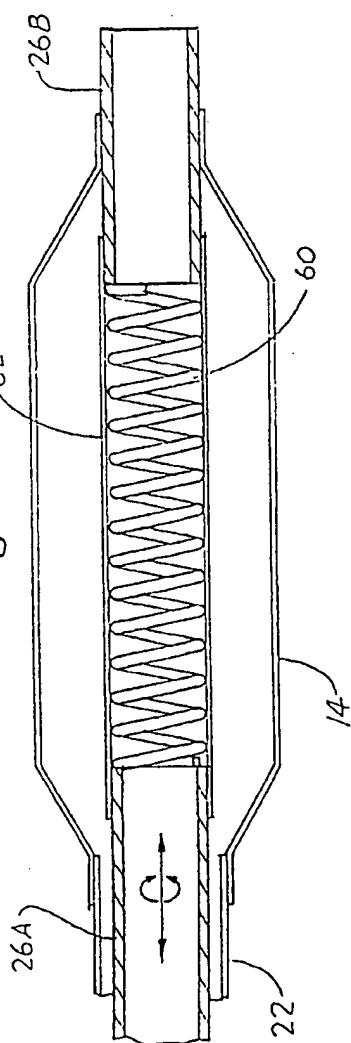
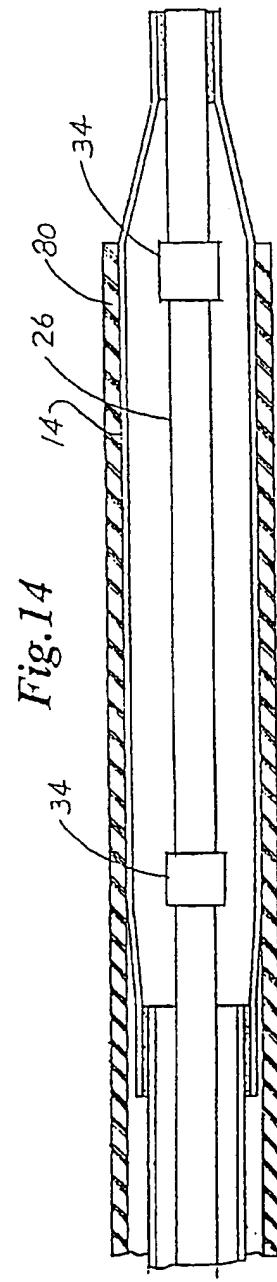
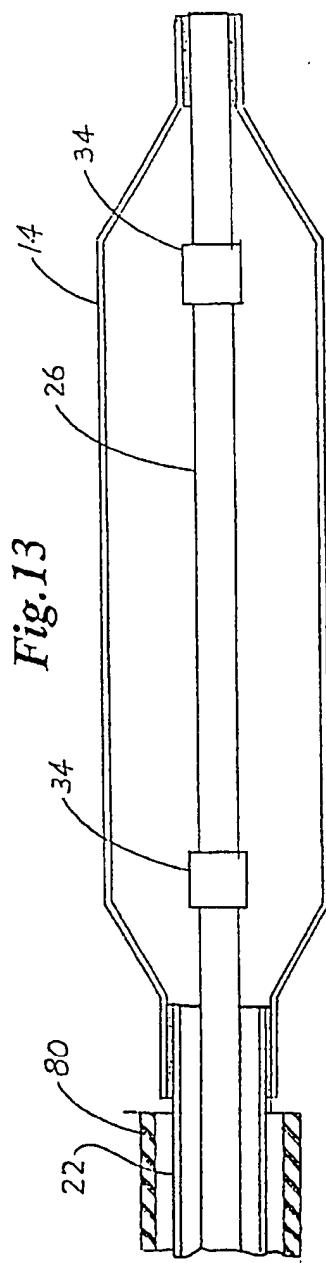
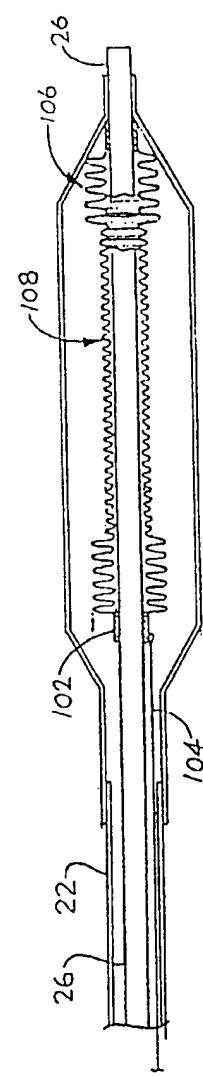
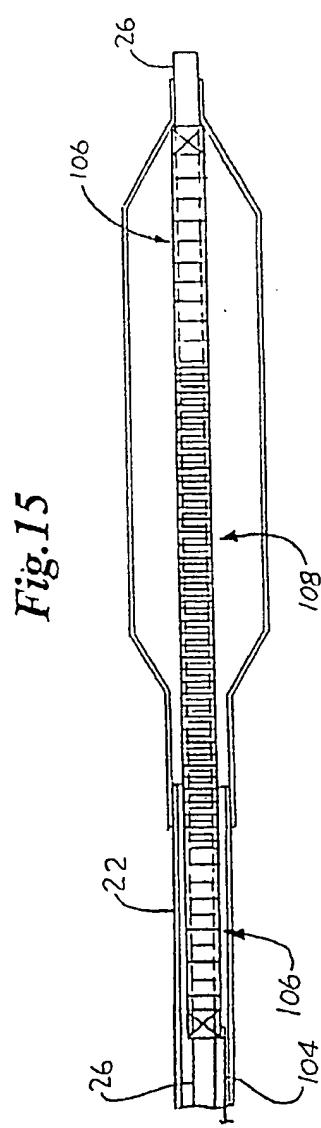


Fig.12







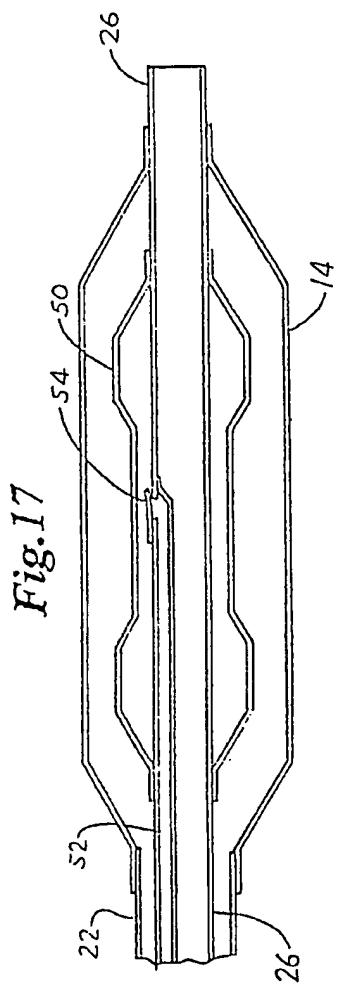
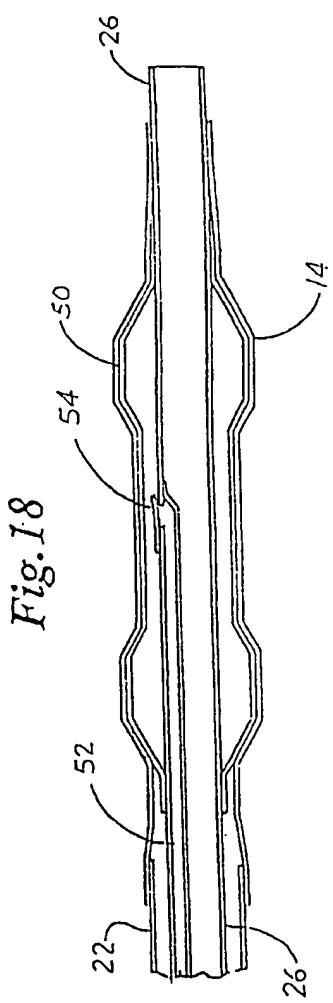
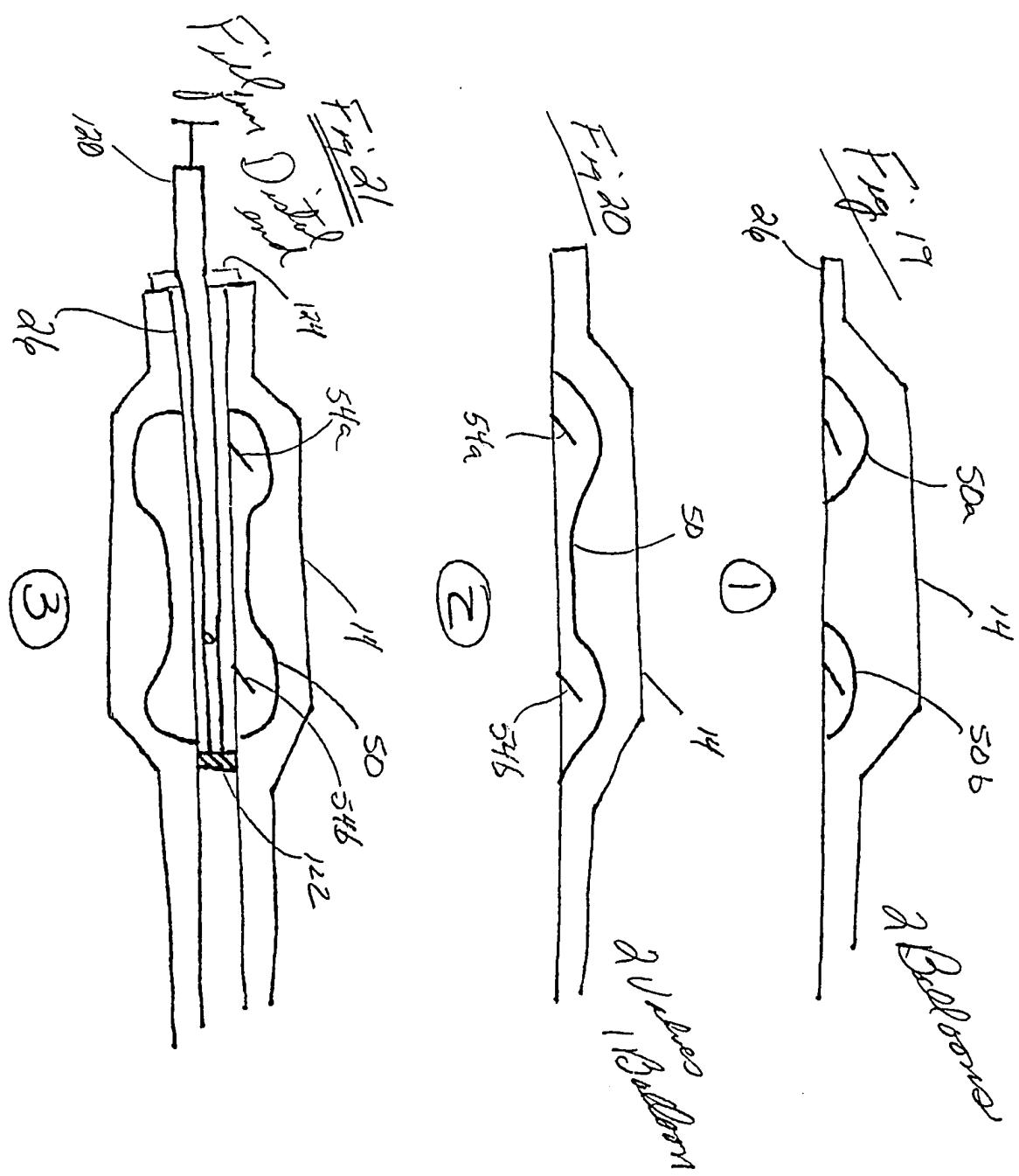


Fig. 17





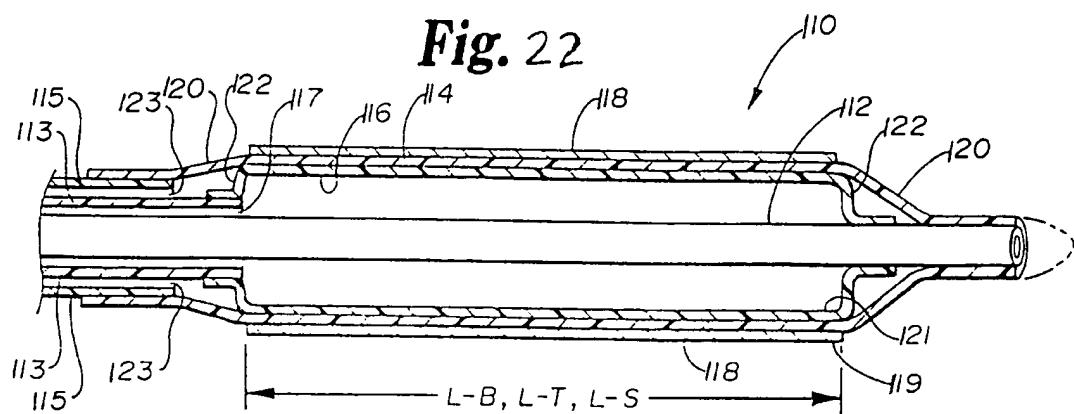
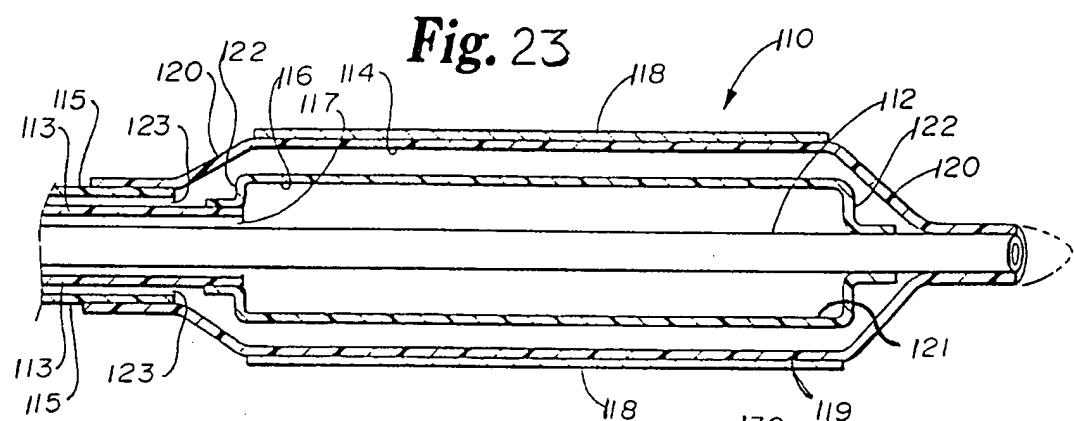
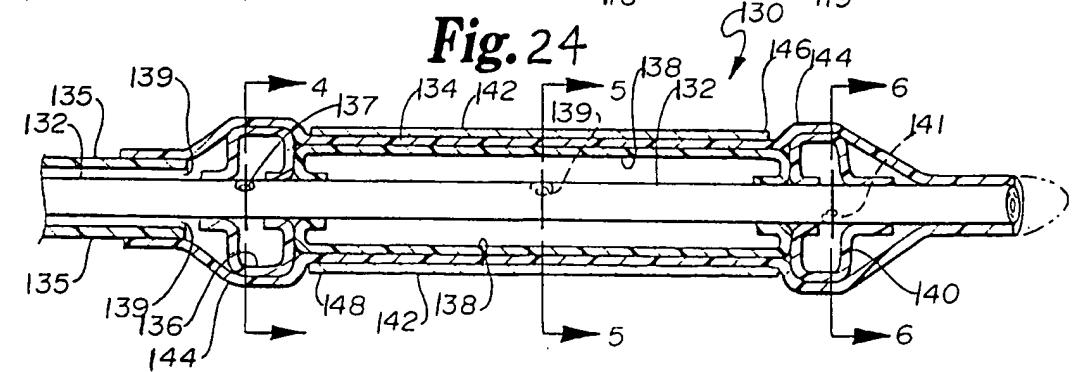
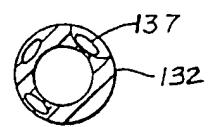
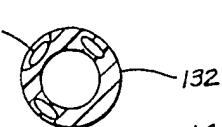
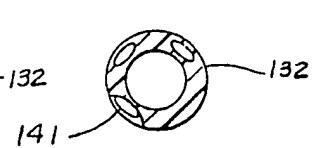
**Fig. 22****Fig. 23****Fig. 24****Fig. 25****Fig. 26****Fig. 27**

Fig. 28

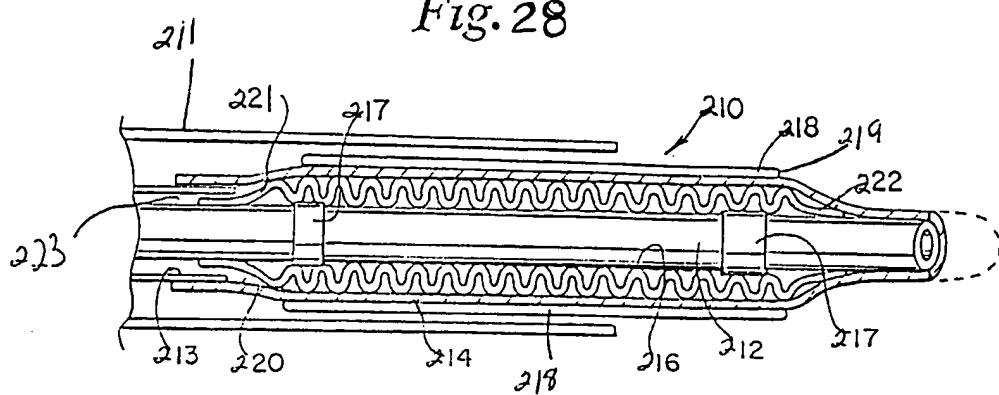


Fig. 29

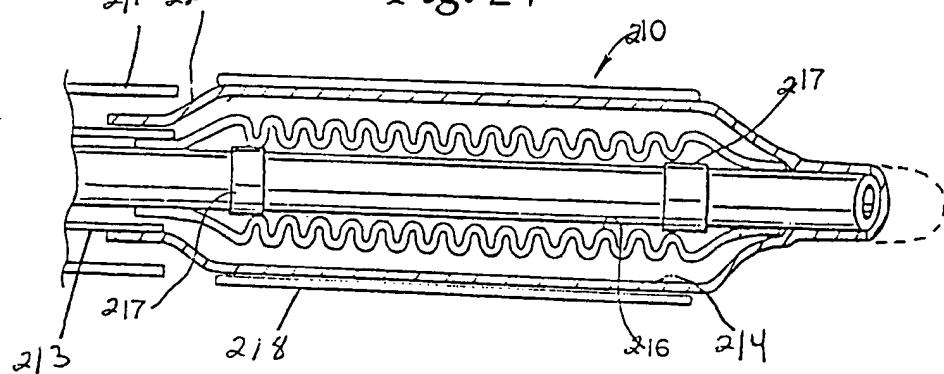
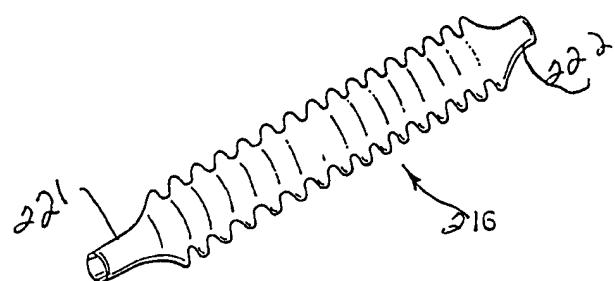


Fig. 30



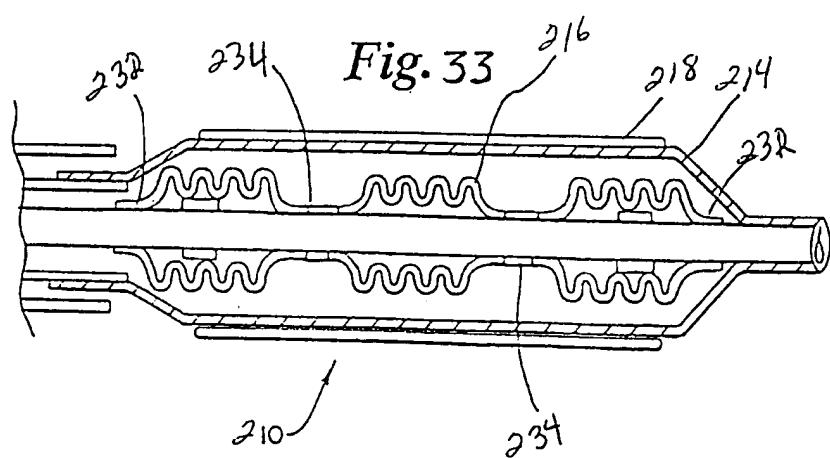
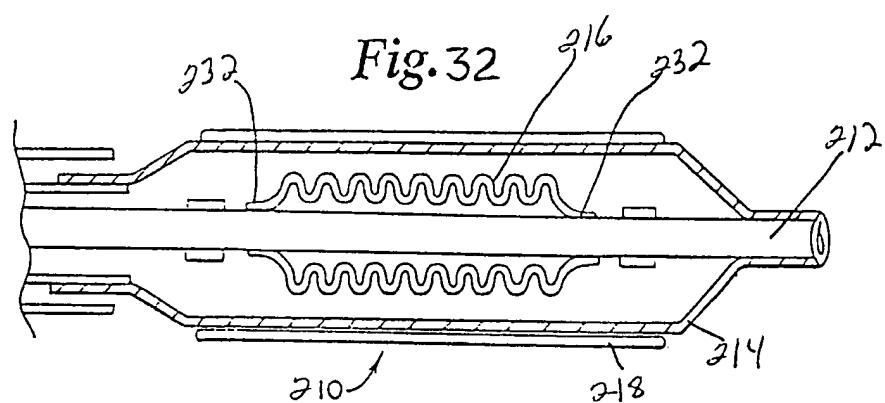
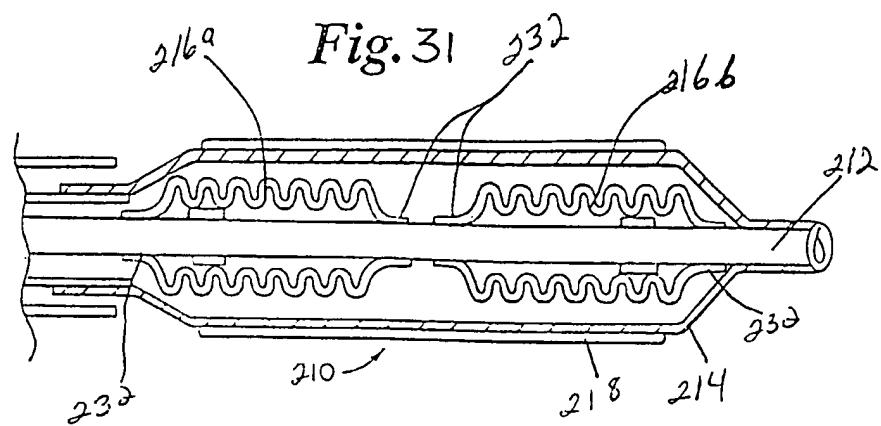


Fig. 34

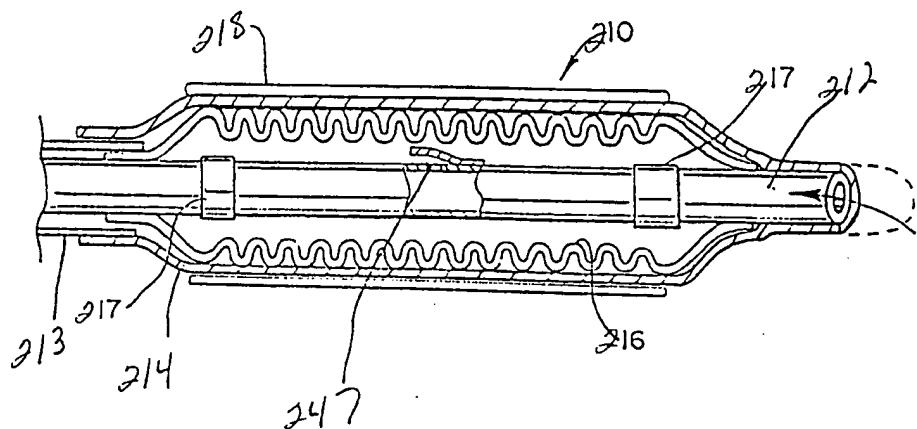


Fig. 35

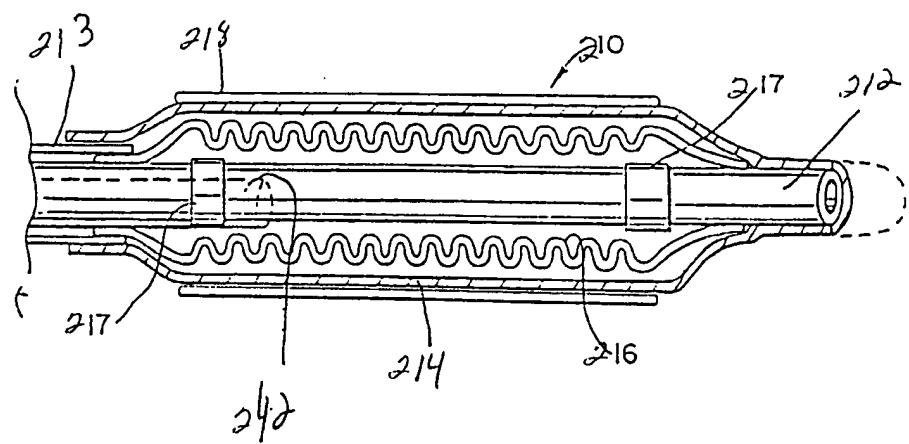


Fig. 36

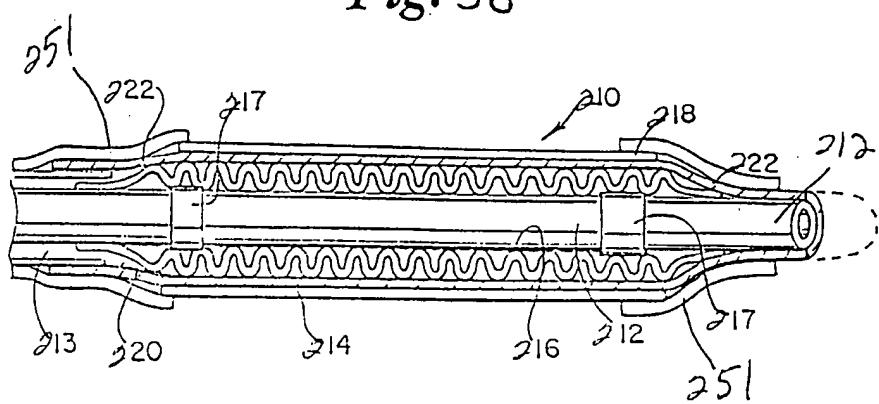
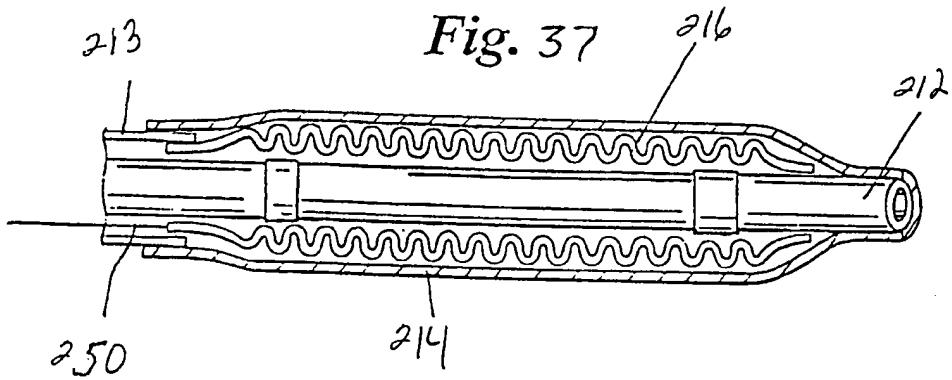
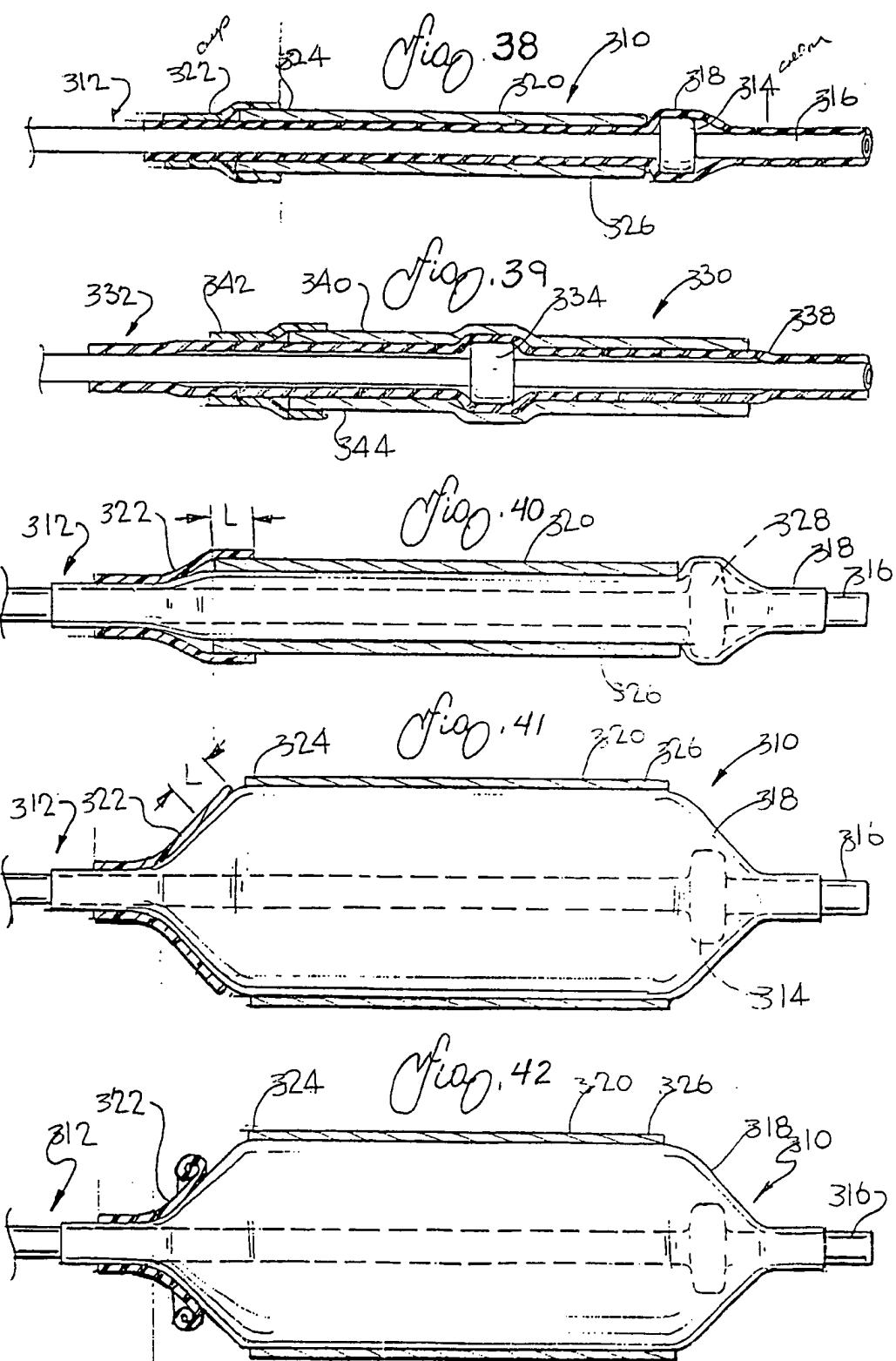
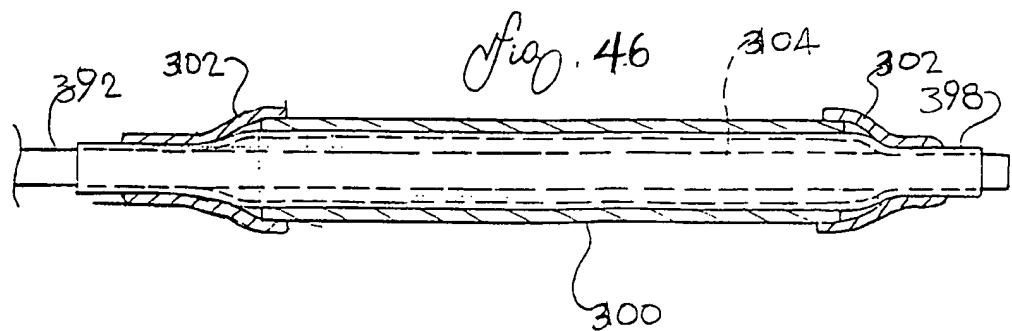
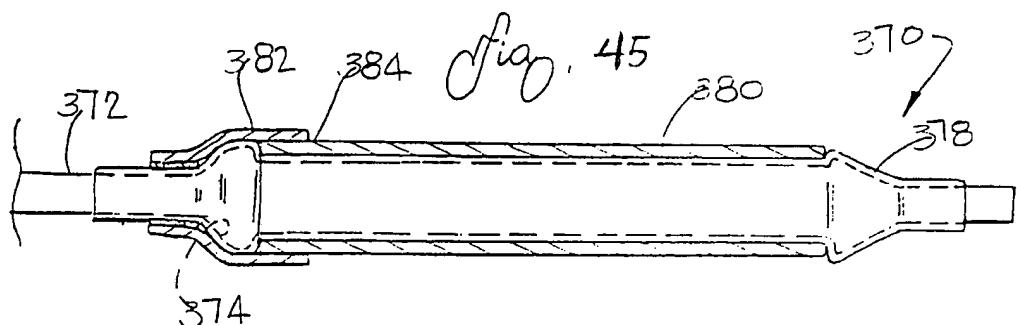
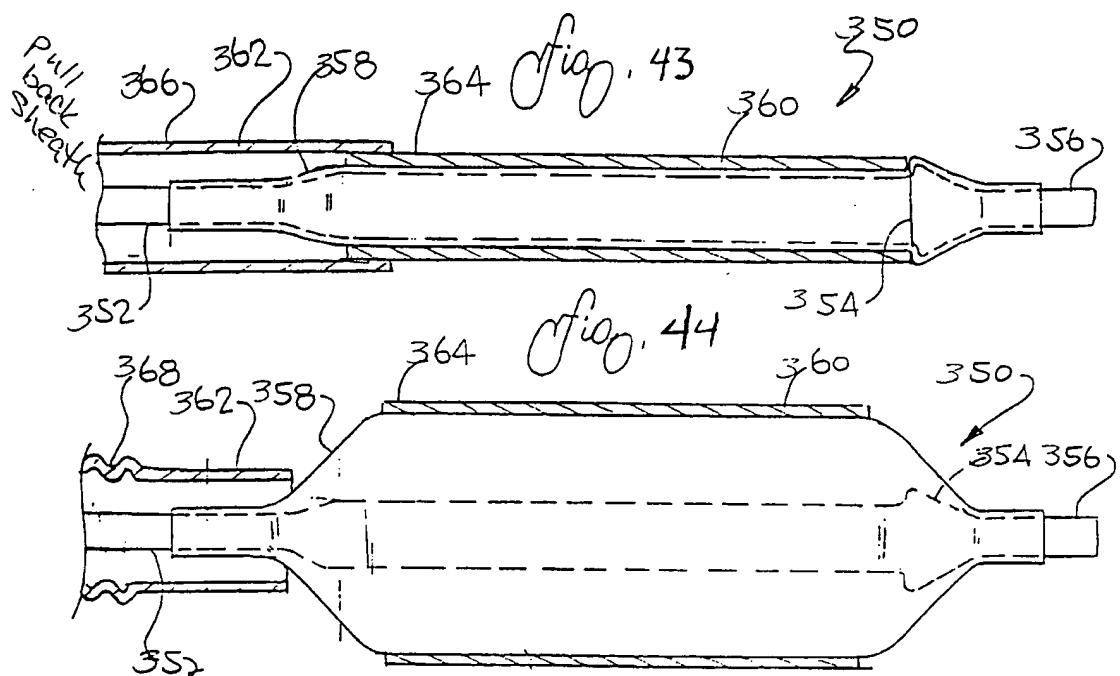


Fig. 37





17/20



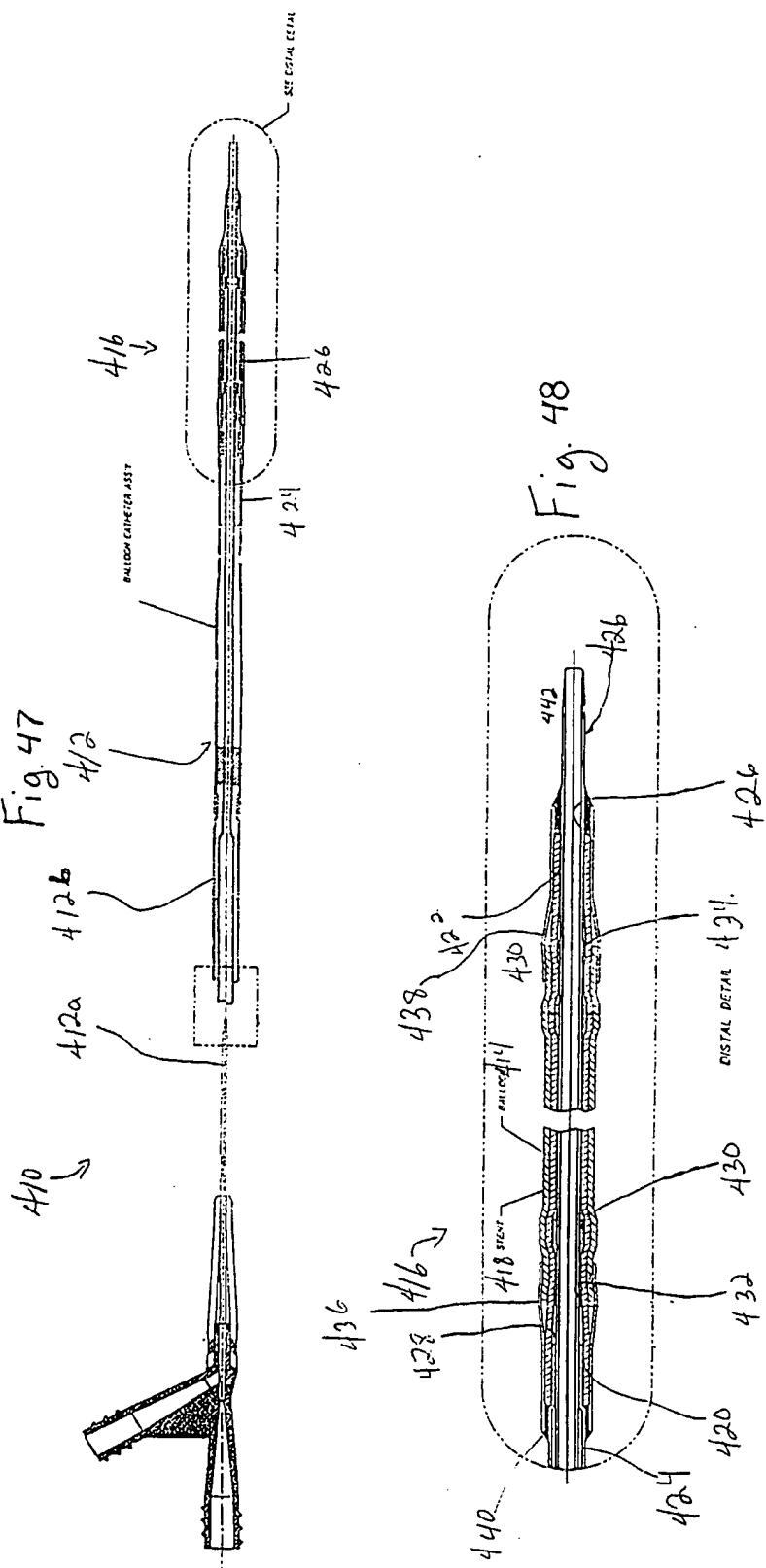


Fig. 49

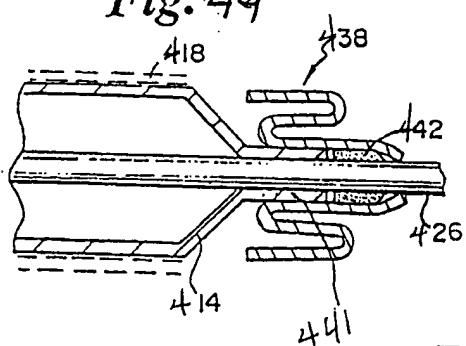


Fig. 50

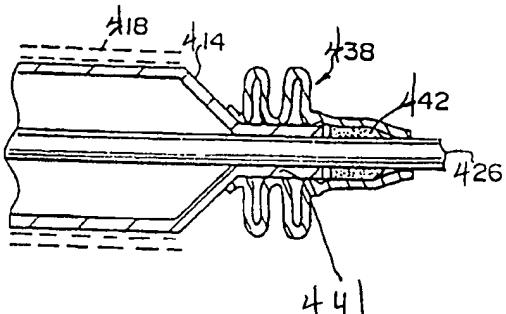


Fig. 51

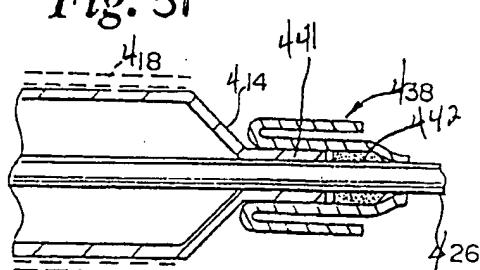


Fig. 52

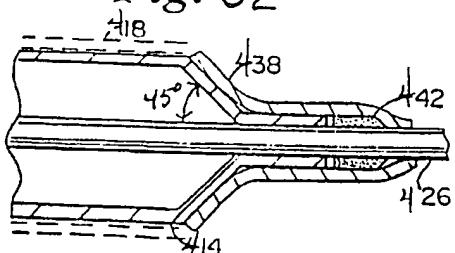
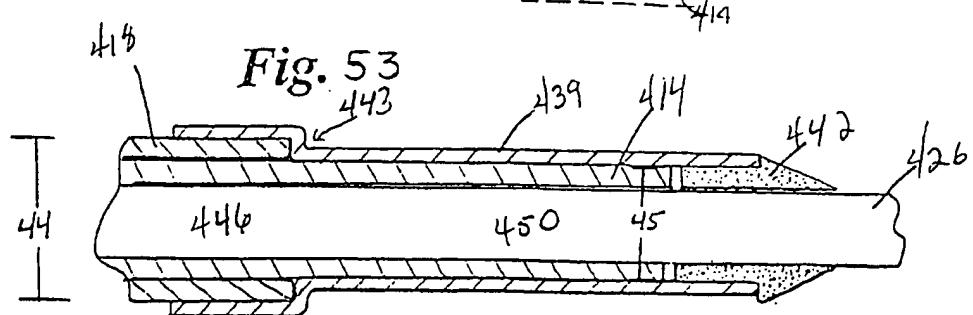


Fig. 53



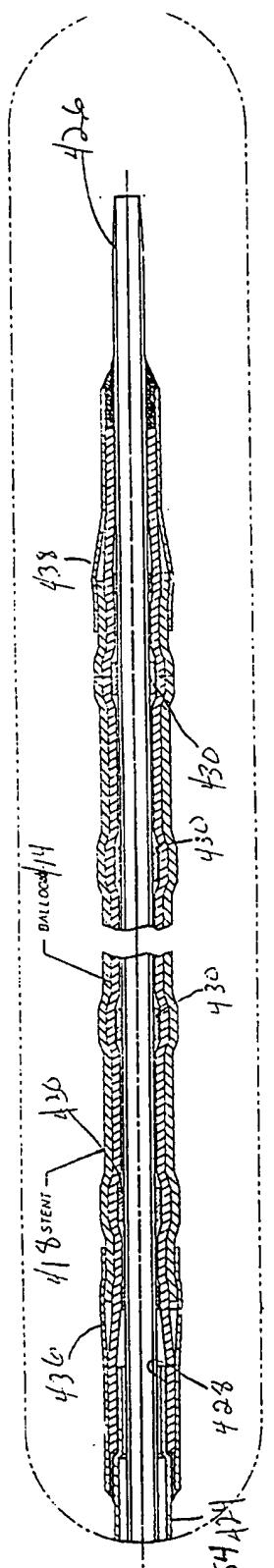


Fig.54

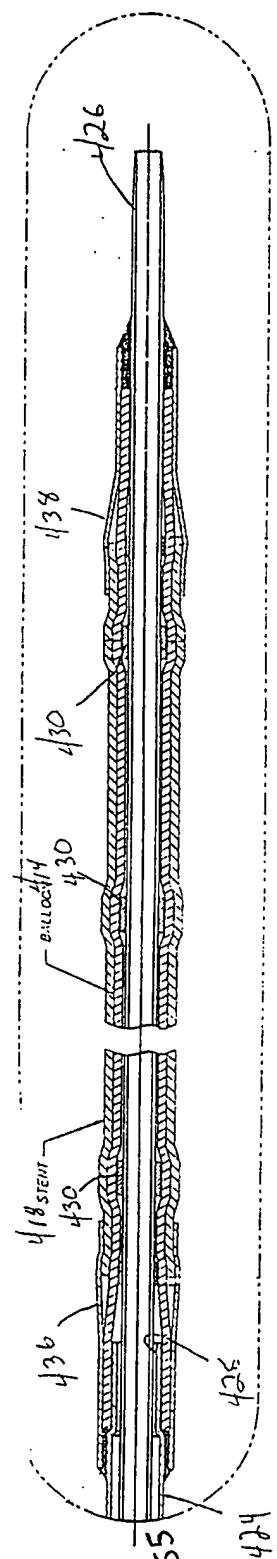


Fig.55

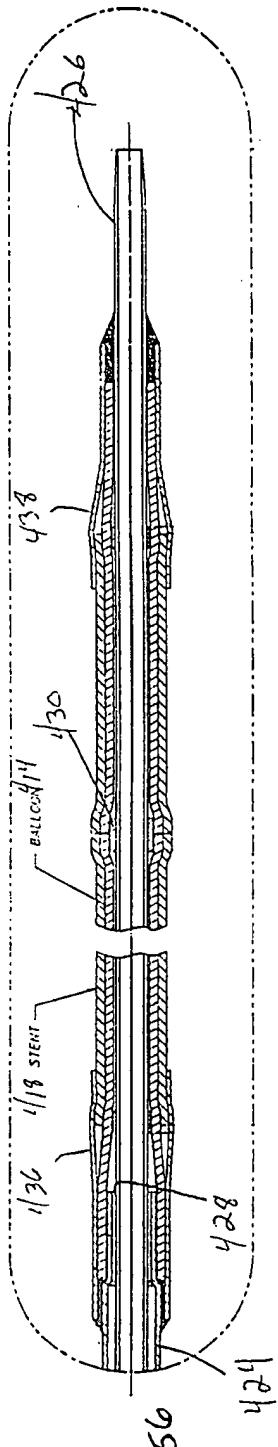


Fig.56

BALLOON DÉTAIL  
SCALE: 20:1

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 97/14980

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61F2/06 A61M25/10

According to International Patent Classification(IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category | Citation of document, with indication, where appropriate, of the relevant passages                   | Relevant to claim No. |
|----------|--|-----------------------|
| A        | US 5 447 497 A (SOGARD ET AL) 5 September 1995<br>see abstract; figures<br>---                       | 1, 26, 27,<br>31, 41  |
| A        | EP 0 553 960 A (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 4 August 1993<br>see abstract; figures<br>--- | 1                     |
| A        | EP 0 266 957 A (C.R.BARD, INC) 11 May 1988<br>---  |                       |
| A        | WO 96 13298 A (INTELLIWIRE, INC.) 9 May 1996<br>-----  |                       |

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

\* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
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- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

|   |  |
|---|--|
| Date of the actual completion of the international search   | Date of mailing of the international search report |
| 8 December 1997   | 18.12.97   |
| Name and mailing address of the ISA   | Authorized officer                                 |
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo rd.<br>Fax: (+31-70) 340-3018 | Smith, C   |

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 97/14980

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 36-40, 53, 54, 92, 94  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2.  Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

The additional search fees were accompanied by the applicant's protest.  
 No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 97/14980

| Patent document cited in search report | Publication date | Patent family member(s)   | Publication date   |
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